2014-1722

# United States Court of Appeals for the Federal Circuit

MEDTRONIC INC.,

*Appellant,*

*v.*

NUVASIVE, INC.,

*Appellee,*

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Appeal from the Patent Trial and Appeal Board
of the U.S. Patent and Trademark Office, Appeal No. 2012-009491
*Inter Partes* Reexamination Control No. 95/001,247

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## APPELLANT'S OPENING BRIEF

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## Certificate of Interest

Under Federal Circuit Rule 47.4, counsel for Requestor-Appellant

Medtronic, Inc. certifies:

1. We represent Medtronic, Inc.
2. Medtronic, Inc. is the real party in interest.
3. No parent corporations or publicly held companies own 10% or more of the stock of Medtronic, Inc.
4. The names of all law firms and the partners or associates that have appeared for Medtronic Inc. at the Patent Trial Appeal Board or are expected to appear in this Court are: Fitzpatrick, Cella, Harper & Scinto: Justin J. Oliver; Nina Shreve and Stephen E. Belisle.

October 20, 2014

/s/ Nina Shreve
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## Table of Abbreviations

| Abbreviation | Meaning |
|---|---|
| '058 patent or Miles | U.S. Patent No. 7,582,058 |
| A_____ | Joint Appendix page(s) |
| Brock | U.S. Patent No. 6,810,281 |
| EMG | Electromyographic |
| Epoch | Epoch 2000 Neurological Workstation 510(k), U.S. Food and Drug Administration No. K971819 (December 30, 1997) |
| Examiner | PTO reexamination examiner |
| Finneran | U.S. Patent No. 6,004,312 |
| Foley | U.S. Patent No. 6,152,871 |
| Kelleher | Kelleher Int'l Publication No. WO 01/37728 A1 |
| Koros patent or Koros | U.S. Patent No. 6,139,493 |
| Marino | Marino Int'l Publication No. WO 00/38574 A1 |
| Mathews | U.S. Patent No. 6,206,826 |
| Mathews Decl. | Declaration of Hallett Mathews, M.D. under 37 C.F.R. §1.132 |
| Michelson | U.S. Patent No. 5,772,661 |
| NuVasive | NuVasive, Inc. |
| Medtronic | Medtronic, Inc. |
| Prass | U.S. Patent No. 6,306,100 |
| PTAB or Board | Patent Trial and Appeal Board |
| PTO or Office | United States Patent and Trademark Office |
| POSA | Person of Ordinary Skill in the Art |

All emphasis is added unless otherwise indicated.

## Statement of Related Cases

No other appeal from the PTAB in connection with the reexamination proceeding now on appeal was before this or any other court.

No other case is pending in this or any other court that will directly affect, or be directly affected by, this Court's decision in the pending appeal.

## Jurisdictional Statement

Medtronic is the third party requestor in an inter partes reexamination of NuVasive's '058 patent and appeals two of the Board's decisions, which issued on April 15, 2014. 37 C.F.R. 1.983(a).

The statutory bases for jurisdiction of this Court to hear the appeal are 28 U.S.C. §1295(a)(4)(A) and 35 U.S.C. §141. A Notice of Appeal was timely filed on June 13, 2014. 35 U.S.C. §142.

All parties' rights to request rehearing have been exhausted, and so the PTAB's decision is final and appealable by any party to the appeal to the Board. 37 C.F.R. 41.81.

## Introduction

This is an appeal from two decisions by the Patent Trial and Appeal Board ("PTAB") regarding NuVasive's U.S. Patent No. 7,582,058 (the "'058 patent"), which relates to nerve detection systems and methods used during spine surgery when accessing a target site.

Shortly after the '058 patent issued, Medtronic requested that the U.S. Patent and Trademark Office ("PTO" or "Office") conduct an inter partes reexamination, which the Office granted. The PTO reexamination examiner ("Examiner") adopted 16 of Medtronic's 18 proposed grounds of rejection and found that each of the prior art references cited by Medtronic raised a substantial new question of patentability regarding NuVasive's original claims 1,2,4,5,7,8. NuVasive added 55 claims in response to the Examiner's rejection, but as reexamination progressed, canceled all of its original claims and most of its new claims, so all that remains is independent claim 10 and its dependent claims 11-16 and 19-27.

As compared to the original claims, one of NuVasive's changes in the remaining new claims was to the recitation of detecting nerves. In new claim 10, NuVasive changed claim 4's original recitation of "sensing

a response of *a nerve* depolarized by said stimulation" to read: "sensing *an electromyographic (EMG) response of a muscle coupled to a nerve* depolarized by said stimulation." This change was not relied upon to distinguish the claim from the prior art. What the change did was broaden the claimed subject matter during reexamination, which is strictly forbidden. 35 U.S.C. §314(a).

The inquiry concerning whether a claim is broader asks if the new claim can be infringed by any conceivable product or process which would not have infringed the original claim. *In re Freeman*, 30 F.3d 1459, 1464 (Fed. Cir. 1994) (internal citation omitted). While NuVasive's new and old claims both require nerve depolarization by stimulation, the original claim scope changed from sensing the response of one physiological structure (nerve) to another (muscle). And this change broadened the original claim because muscle can produce an EMG response in ways other than from depolarization of a nerve coupled to it.

The PTAB at first unanimously sided with Medtronic and found NuVasive's claims impermissibly broadened. Because the claim language at issue was not relied upon to distinguish the prior art, NuVasive had the chance to correct the change. Instead, NuVasive

requested rehearing. On rehearing, the Board reversed itself in a split decision.

In its rehearing request NuVasive proposed an inverted inquiry: instead of using the well-settled infringement based test and asking whether the amended claim could conceivably cover something that the original claim did not, NuVasive urged the Board to ask whether the original claim could be broadly interpreted to encompass the later claim. The Board did not conduct NuVasive's inverted inquiry, but nonetheless conducted the wrong analysis, focusing on whether there is written description support for the amended claim. But the prohibition on broadening and the written description requirement are different analyses that serve different purposes. Broadening is strictly prohibited in reexamination because claims notify the public what the patentee regards as the invention, as well as what is still available to the public. The written description requirement ensures that the inventor had possession of the invention when the application was filed and that a POSA can make and use that invention. 35 U.S.C. §112 ¶1. Also, because the specification may disclose information that is not claimed,

the broadening inquiry is logically focused on what is claimed, not what is disclosed.

Medtronic also appeals the Board's failure to adopt proposed grounds of rejection based on the prior art Koros patent and, more fundamentally, its failure to make factual findings based on that patent in its entirety. The question is whether the Koros patent discloses claim 10's element of a "locking member releasably received within a passageway of a retractor blade." While there is no dispute that the Koros patent shows locking members in a blade used in spine surgery, the PTAB concluded that patent did not teach the claimed element, because its locking members are associated with Koros' so-called distractor blades rather than Koros' so-called retractor blades. But viewing the Koros patent in its entirety, as the obviousness analysis requires, the "distractor" blades are so-called because they distract adjacent vertebrae, but they also perform the function of retracting soft tissue, and thus teach that element of NuVasive's claim. In each case, types of tissue are being moved or maneuvered. Also, regardless of the various blades identified in the Koros patent, Medtronic clearly relied upon Koros' screws 83 as being a locking member as recited in

NuVasive's claims. That screw 83 is a locking member has not been challenged.

## Statement of the Issues

1. Did the PTAB err in finding that NuVasive did not broaden its claims by changing "sensing the response of a nerve depolarized by said stimulation" to "sensing the electromyographic (EMG) response of a muscle coupled to a nerve depolarized by said stimulation," when there is no dispute that an EMG response of a muscle can be produced in ways other than from depolarizing a nerve coupled to it?

2. Did the PTAB err in finding non-obvious a "locking member releasably received within a passageway of a retractor blade" when the Koros patent teaches a locking member (screw 83) on a distractor blade, the Koros patent in its entirety makes clear the "distractor" blade functions as a retractor blade, and Medtronic relied upon screw 83 in its proposed rejection?

## Statement of the Case

The PTO granted Medtronic's request for an inter partes reexamination of NuVasive's '058 patent and the Examiner rejected all the challenged claims as obvious. A155, 157-61; A122-23. In response, NuVasive added 55 new claims. A181; A228-39. Medtronic maintained its obviousness challenge and explained that NuVasive's new claims were improperly broader than the original claims, in violation of the strict statutory prohibition against broadening claims during reexamination. 35 U.S.C. §314(a); A323-25.[1] Medtronic also proposed obviousness rejections based, in part, on the Koros patent, which was cited during the '058 patent's prosecution, but not in relation to the new elements NuVasive added to its claims. A350-54; A359,362,374-75; A381,384,395; A1511-15,1524.

The Examiner agreed that the Koros patent raised a significant new question of patentability, but did not adopt proposed grounds of rejection based on that reference, and did not address Medtronic's

[1] 35 U.S.C. §314(a) was amended by the Leahy-Smith America Invents Act, dated September 16, 2011. *See* Pub.L. No. 112-29, §6, 125 Stat. 284, 299-305 (2011). The amendments to §314 do not apply here because the request for inter partes reexamination was filed before the date of enactment, September 16, 2011. *Id.* Thus, all references to §314 in this brief are made to the previous version of the statute.

broadening challenge at all in finding all of NuVasive's claims patentable. A402, 408-09.

Medtronic appealed to the PTAB, where the Board acknowledged Medtronic was "presented with the extraordinary situation of appealing rejections that the Examiner has not adopted, without sufficient reasoning." A1107-08,1111-12. The PTAB unanimously reversed the Examiner and instituted rejections against all the claims under reexamination. A1227,1269-72. The PTAB found NuVasive's claims 10-50 were improperly broadened. A1234-37. The PTAB also found NuVasive's claims 30-50 obvious in view of proposed grounds of rejection (including the Koros patent). A1244-68, 1271. The PTAB did not adopt prior art rejections involving the Koros patent against claim 10. A1264-66,1272.

In response to the Board's decision, NuVasive cancelled all of the claims except for 10-16 and 19-28, and requested rehearing of the broadening rejection. A1275-79, A1282. Medtronic requested rehearing of the PTAB's decision not to adopt the obviousness rejections. A1294-1304. In the decisions on rehearing, the PTAB maintained its refusal to adopt rejections of claims 10-29 based on the Koros patent and—in a split

decision that included a written dissent—withdrew its rejection based on broadening. A1-16, A17-26. It is these decisions of the Board that Medtronic now challenges.

## Statement of the Facts

### I. Statutory Background

#### A. There is a Strict Statutory Prohibition against Broadening Claims during Reexamination

During reexamination proceedings, patentees may amend existing claims or propose new claims, but no amended or new claim can broaden the patent's original claims. 35 U.S.C. §314(a). A claim is broader if it "contains within its scope any conceivable product or process which would not have infringed the [original] patent." *Tillotson, Ltd. v. Walbro Corp.*, 831 F.2d 1033, 1037 n.2 (Fed. Cir. 1987). Claims broadened during reexamination are invalid. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1583-84 (Fed. Cir. 1995).

#### B. Determining Whether a Claim is Obvious Requires Examining the Prior Art in Its Entirety

Under section 103 of the Patent Act, claimed subject matter is obvious if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. §103(a). Prior art is examined in its entirety to determine what it teaches the POSA. *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965).

## II. Science at Issue

The '058 patent is entitled "Surgical Access System and Related Methods" and its current claims are directed to systems and methods for surgically accessing the spine using minimally invasive surgical techniques that include nerve monitoring. A27-72.

### A. Minimally Invasive Surgical Techniques Were a Noteworthy Trend When NuVasive Filed Its Application

Employing newer minimally invasive surgical techniques over traditional open surgical methods was a "noteworthy trend in the medical community" when NuVasive filed its patent application, which claims priority to June 26, 2002. A64 (Miles) (col.1:35-38).

In traditional open surgery, the surgeon makes a large incision and cuts muscle and other tissue, or moves them aside, to see and work on the spine. *Id.* (col.1:38-43). Cutting through tissue and retracting it in this manner can cause damage, affect more tissue than is required to see and access the surgical target site, and increases the potential to damage nerves. *Id.* (col.2:21-25); A1013,1036 (Foley) (col.1:21-31).

A minimally invasive technique accesses the surgical target site using a smaller incision or incisions than is used in traditional open surgery. A64 (Miles) (col.1:36-38, 1:43-48). A corridor is created from the

incision to the target site at the spine. *Id.* (col.1:52-55); A1057,1064 (Koros) (col. 1:22-25). Systems to create corridors were known in the art before the '058 patent application was filed. A64 (Miles) (col.1:52-2:20); A1064 (Koros) (col.1:26-47). Creating and widening the corridor is often referred to as "distracting," and is typically achieved by inserting a series of progressively larger dilators, which gradually separate the muscle to enlarge the corridor so the surgeon can access the spine. A64 (Miles) (Abstract, col.1:62-2:20); A997,1010 (Mathews) (col.10:53-11:2); A1507,1509 (Mathews Decl.) (¶7:9-10). NuVasive terms the final widening of the corridor "retracting." A65 (Miles) (col.3:8-15). Once retractor blades are in place, the dilators are removed, leaving a working corridor through which the surgery is performed. *Id.* (col.3:5-15); A1065 (Koros) (col.3:1-15, 4:24-31). The distinction between distraction and retraction can be a matter of semantics. A1065 (Koros) (col.3:1-18). When the procedure is finished, the tissue returns to its original position. Minimally invasive techniques cause fewer traumas to the tissue, which allows patients a quicker recovery with less pain. A64 (Miles) (col.1:43-51); A1006 (Mathews) (col.1:58-2:5).

Accessing the spine for surgery is a delicate procedure because the spine contains neural structures: the spinal cord; nerve roots that radiate out through each side of each vertebra; and nerves that branch from the nerve roots throughout the body. A64 (Miles) (col.2:21-39); A1006 (Mathews) (col.1:41-57).

These neural structures carry signals from the brain to the body and vice versa. A1343-45 (Kelleher) (ll.15-17). Creating a corridor from the incision to the spine carries a risk of damaging nerves and nerve roots. A64 (Miles) (col.2:21-25); A1345 (Kelleher) (ll.13-19); A1507-08 (Mathews Decl.) (¶5:6-7). A damaged nerve may impair the signals between the spinal cord and the part of the body innervated by that nerve. A64 (Miles) (col.2:21-39). This can affect sensation and muscle contraction, or, more seriously, cause organ failure, paralysis and in extreme cases, death. Relevant to this appeal are the processes of creating a corridor from the incision to the surgical target site and sensing whether nerves are being affected so damage may be avoided.

### 1. NuVasive Claims a "Locking Member" "Releasably Received Within a Passageway of the Retractor Blade"

NuVasive claims bladed retractor tools, which "have been known since prehistoric times." A1173-74, 1216 (ll.17-21). Relevant to this

appeal is Claim 10's recitation of a "locking member releasably received within a passageway of the first retractor blade." Claim 10 reads in relevant part (A230-31):

> "… [a] pair of directly opposing retractor blades being releasably lockable to an external assembly having handle arms, said pair of directly opposing retractor blades comprising first and second retractor blades having similarly shaped main body elements, wherein a position of the second rectractor blade is adjustable relative to the first retractor blade after the first retractor blade is advanced along the lateral, trans-psoas path to the spinal target side, and said retractor assembly further comprising a first *locking member releasably received within a passageway of the first retractor blade* such that a distal region of the first locking member penetrates laterally into the lumbar spine to secure a distal end of the first retractor blade relative to the lumbar spine…"

A locking mechanism to fix the blades so they will not move during surgery was known in the art. For example, the Koros patent discloses locking members—what it calls "fixation screws"—that fasten blades to vertebrae to keep the retracting/distracting apparatus from moving during surgery. A1061,1064,1066-67 (Koros) (col.1:48-51, 5:1-9, 7:24-29, Fig.5).

### 2. Surgeons Aim To Avoid Contacting Nerves By, For Example, Monitoring Nerve Activity

Patients may be monitored while the corridor is created, retracted and maintained to ensure that nerves are not being contacted and possibly damaged. A1345 (Kelleher) (ll.9-19). Monitoring for possible nerve damage during the procedure was also known in the art when NuVasive filed its patent application and can include introducing electrical stimulation through the surgical instruments. A1347 (ll.30-34), A1348 (ll.1-24), 1360 (ll.16-23), 1376 (Kelleher). When a nerve is at rest (not stimulated) it is polarized, meaning the cell has a negative charge on the inside and a positive charge on the outside. When electrical stimulation is introduced close to a nerve it causes the nerve to depolarize. A68 (Miles) (col.10:51-56). Depolarization means the nerve cell changes its charge so that it is positive on the inside and negative outside. This depolarization continues along the length of the nerve (absent neurological injury) and, like a domino effect, carries the signal from one nerve cell to the next.

Depolarization can be monitored in variety of ways. The activity of the nerve can be sensed directly. *See e.g.* A1390-92 (Marino), 1492 (ll.3-7); A68 (Miles) (col.9:55-58). Alternatively, since some nerves innervate

muscle, the depolarization may cause muscle activity, which may also be measured. *Id.* NuVasive's current claims sense an electromyographic (EMG) response of a muscle. A1276-77. EMG is a well-known method in the art for monitoring electrical activity typically associated with any muscle movement such as, for example, contraction. A68 (Miles) (col.9:61-67); A1509-10 (Mathews Decl.) (¶8:5-12).

As the '058 patent acknowledges, recorded EMG activity in a muscle "may" indicate there are neural structures near the distraction and/or retraction assembly, but not necessarily. A65,68 (Miles) (col.4:15-17, 9:58-60). A muscle's EMG activity could result from a host of activities, so much so a known problem in the art is distinguishing between the causes of recorded EMG responses. A1366 (Kelleher) (ll.18-26).

For example, mechanical stimulation of the muscle can provoke an EMG response; as can incidental irritation of a nerve associated with that muscle caused by temperature fluctuations in the surgical area, irrigating the area with saline, cauterizing or ablating nearby tissue, chemical irritation, drying and so on. A1449,1462-64 (Prass) (col.1:66-2:3, 4:1-5, 5:23-45); A793 (Epoch). Involuntary movement (muscle tremors,

spasms) or voluntary movement can likewise result in a measurable EMG response separate from electrical stimulation of the nerve. A1069,1096-97 (Finneran) (col.5:17-24, 7:32-44). Also, one muscle may be connected to nerves originating at different spinal nerve roots, and EMG responses recorded at a muscle may originate at a nerve root exiting from a level of the spine different from the level at which the surgery is performed (e.g. at a different level than the electrical stimulation). A940 (Epoch) (col.2:13-22). So a sensed EMG response of a muscle could indicate physiological activity unrelated to stimulation of a particular nerve.

## III. Reexamination Proceedings before the Examiner

### A. PTO Granted Medtronic's Reexamination Request and the Examiner Found All Challenged Claims Obvious

NuVasive's '058 patent issued on September 1, 2009, with 9 claims. A27,72. Shortly after, Medtronic requested inter partes reexamination of claims 1,2,4,5,7,8, offering 18 grounds of rejection for obviousness under 35 U.S.C. §103(a). A77; A156-59. The PTO granted Medtronic's request on December 17, 2009. A153,155. That same day, the Examiner adopted 16 of Medtronic's grounds of rejection and found each of 15 pieces of prior

art raised a substantial new question of patentability regarding NuVasive's claims. A120-50.

### 1. In Response to the Examiner's Rejection, NuVasive Added 55 Claims, Including Claim 10 Which Amended Original Claim 4 and Includes New Features

In response to the Examiner's rejection, NuVasive added 55 new claims, including independent claim 10, which is based on original claim 4. A240; A228-39. Original claim 4 reads "sensing a response of a nerve depolarized by said stimulation." Amended claim 10 changed the sensed response from the nerve to the muscle, adding to claim 4 the italicized text: "sensing a*n electromyographic (EMG)* response of a *muscle coupled to a* nerve depolarized by said stimulation." A228-29,230-31. The step of "sensing a response of a nerve depolarized by said stimulation" does not appear in claim 10.[2] *Id.*

NuVasive did not rely on this amendment to overcome prior art, and did not argue claim 10 is patentable because of the amended sensing feature. A240,281-82. Nor did NuVasive point out the change in the sensing step to the Examiner. Instead NuVasive stated, without

[2] Claim 10 contains 626 words; only the portions of the claim relevant to the appeal are reproduced in this brief. Claim 10 is found in its entirety in the Appendix. (A230-31).

elaboration, that "new claim 10 is not broader than the scope of original claim 4." A281.

NuVasive's new claims 10-29 and 33-36 also added features including a "locking member." Specifically, claim 10 recites a "locking member releasably received within a passageway of the first retractor blade" that penetrates the spine to secure retractor blades. A231 (ll.7-8).

### 2. Medtronic Proposed Rejections Based on Impermissible Broadening, and Obviousness In View of the Koros Patent

In response to NuVasive's amendment from sensing the response from one physiological structure (a nerve) to another (muscle), Medtronic proposed that claim 10 and its dependent claims be rejected under 35 U.S.C. §314(a) for impermissible broadening. A323-25. Medtronic also proposed various obviousness rejections of claim 10 and its dependent claims based on combinations of prior art including Marino, Mathews, Michelson, Kelleher, Finneran, Foley and the Koros patent. A349-53,357-58. In particular, Medtronic relied upon the Koros patent as teaching the new "locking member" feature. A350-52.

### 3. The Examiner Found NuVasive's Claims Patentable, Without Addressing Broadening, and Despite Finding

the Koros Patent Raised a Significant New Question of Patentability

The Examiner found the pending original and new claims patentable. In so doing, she did not address Medtronic's proposed rejection based on broadening. A400-02. The Examiner agreed with Medtronic that the Koros patent raised a significant new question of patentability because "Koros teaches a multi-bladed retractor assembly that comprises locking members in the form of screws 83, with distal portions of the screws penetrating laterally into vertebrae to secure the retractor blades" and therefore "teaches features cited in the requested claims" so "a reasonable examiner would find the teaching of [the] Koros [patent] to be important in deciding whether or not a claim is patentable." A408-09. Despite this conclusion, the Examiner did not adopt grounds of rejection based on the Koros patent. A402,410.

## IV. PTAB Proceedings

Medtronic appealed the Examiner's decisions on claims 1,2,4-8 and 10-65. A429-33. In particular, Medtronic appealed the Examiner's failure to address broadening and refusal to adopt Medtronic's prior art grounds of rejection based on the Koros patent to the PTAB. *Id.* Medtronic noted that the Examiner failed to adopt, or address in any

manner, Medtronic's proposed broadening rejection; and merely cited to NuVasive's earlier-filed response as reasons for patentability, without discussing the issues raised by the newly cited prior art. A434,478-84.

Recognizing that Medtronic was "presented with the extraordinary situation of appealing rejections that the Examiner has not adopted, without sufficient reasoning" the PTAB allowed Medtronic to submit additional pages on appeal. A1106-08,1112. Specifically, the Board noted the Examiner's only explanation of her finding of patentabiliy was a reference to NuVasive's brief, which was filed before Medtronic submitted comments, and the Examiner's refusal was "silent as to the specific reasons why the proposed rejections were not adopted." A1112.

### A. Medtronic's Proposed Broadening Rejection

#### 1. The PTAB Unanimously Found NuVasive Improperly Broadened the Scope of Its Claims

On appeal to the PTAB, NuVasive argued that there are many ways of sensing the response of a nerve as in claim 4, and sensing the EMG response of a muscle coupled to a nerve is one of those options, such that new claim 10 is narrower than original claim 4. A1114,1140-41. NuVasive also asserted that claim 10 includes "every single element of

original claim 4 along with many additional narrowing limitations." A1140.

Medtronic countered that claim 10 does not include every limitation of claim 4, because claim 4 sensed the response of a nerve and claim 10 senses the response of a muscle. A1147,1167-68. Further, that claim 10 recites a muscle that is "coupled" to a nerve does not change the fact that muscle and nerve are different anatomical structures, and sensing the response of one is not the same as sensing the response of another. *Id.* Medtronic provided examples of how claim 10 could be infringed where claim 4 would not, which is the definition of broadening. *Id.* For example, involuntary muscle spasm or voluntary muscle movement by the patient can result in an EMG response of a muscle without a signal from a nerve depolarized by stimulation, and would infringe claim 10 but not claim 4. A1168. Also, a muscle is innervated by nerves from multiple levels of the spine, so even if electrical stimulation is applied at one level during surgery, a muscle may produce an EMG response because of activity at a different level of the spine. *Id.* Further, depolarizing a nerve by stimulation would not result in EMG activity where the signal is blocked due to neurological injury. *Id.* Consequently, sensing the EMG

response of a muscle as in claim 10 may not indicate "a response of a nerve depolarized by said stimulation," even if the nerve and muscle are coupled to each other. *Id.*

The PTAB agreed with Medtronic that claim 10 was improperly broadened because "sensing a response of a nerve, as in claim 4, is not the same act as sensing the response of a muscle, as in claim 10." A1226-1228,1234-37. The Board rejected NuVasive's argument that claim 10 is narrower as "merely argument of counsel" unsupported by "citation to any portion of the record." A1236-37.

The PTAB concluded that its finding amounted to a reversal of the Examiner, even though the Examiner did not refer to Medtronic's proposed broadening rejection in her decision. A1237. ("[That] the rejections were not applied is effectively a decision by the Examiner favorable to the patentability of those claims.").

The PTAB also adopted grounds of rejection based on the prior art (including the Koros patent) for remaining claims *not* rejected as improperly broadened. A1267-71.

### 2. NuVasive Cancelled Most of Its Claims and Requested Rehearing

Following the PTAB's decision, NuVasive cancelled its original claims and most of its new claims—leaving just independent claim 10 and its dependent claims 11-16 and 19-27 (the claims without a pending prior art rejection)—and requested that the PTAB reconsider its decision on the broadening issue. A1275-79; A1282.

NuVasive's proposed analysis focused on the original—not amended—claims by advocating that the broadest reasonable interpretation should apply to claim 4 to determine whether it could be interpreted to cover claim 10. A1283-84. Continuing its focus on the original claim, NuVasive framed the question as "whether [original claim 4's] 'sensing a response of a nerve depolarized by said stimulation' can be performed by [claim 10's] sensing a muscle coupled to a nerve depolarized by the stimulation." A1287. NuVasive concluded that sensing a response of a nerve in claim 4 is broader than claim 10 because the specification supports interpreting "sensing a nerve" to include sensing a response of a muscle coupled to a nerve. A1285-87.

Medtronic responded that NuVasive's proposed analysis was wrong and inverts the proper analysis because the question is not whether

claim 4 can be broadly interpreted to cover a possible technical aspect of claim 10, but whether the new claim 10 could cover any process not covered by claim 4. A1305-16, *esp.*1306-07. And the proper analysis focuses on the broadest reasonable interpretation of *both* the original and amended claims, not just the original claim. A1314-15.

Applying its analysis, Medtronic pointed out that NuVasive's original limitation of sensing a response of a nerve can literally refer to sensing the activity of the nerve. A1308-09; A1318,1329 (Brock) (col.10:30-52), A1330 (col.11:10-19, 12:25-28), 1331 (col.14:18-21), 1332 (col.16:42-54). Medtronic did not dispute that an EMG response of a muscle may be caused by electrical stimulation of a nerve coupled to it as in claim 4. However, an EMG response of a muscle may be caused by other things, which the '058 patent itself acknowledges and is a scientific fact that NuVasive does not challenge. A1309; A65,68 (Miles) (col.4:15-17, 9:58-60). These other causes would infringe claim 10 but not claim 4, which is the proper test to determine whether a claim is impermissibly broader. A1305,1308-15.

As to the specification, Medtronic pointed out that, even if it suggests a different intended recitation, the *actual* recitation in the claim

was originally based on nerve activity. If NuVasive wished to correct a drafting error in the claims, reexamination was not the proper process to remedy such an error. A1316.

Also, NuVasive had the opportunity after the PTAB's decision to go back to the original language to correct the problem, but chose to keep the amended language and request rehearing. A1226-27,1273-74; A1-2,15 (FN4).

### 3. In a Split Decision, the PTAB Reversed Its Earlier Decision and Found Claim 10 Was Not Broadened

A split Board reversed its earlier decision and found claim 10 was not broadened. A1-16. The majority concluded that, while muscles may produce activity apart from activity of the nerve, those responses are not within claim 10's scope. A7-8. That conclusion, the PTAB explained, is supported by the specification of the '058 patent, which is "not concerned with any direct sensing of a nerve." A8.

In dissent, Administrative Judge Song laid out the reasons why the Board's initial determination is correct. A9-16. *First*, claims 4 and 10 "recite sensing responses of different physiological structures" and therefore "encompass different subject matter." A10. *Second*, NuVasive's argument that the Board interpreted claim 4 to require "presumably,

that the claimed 'sensing' be done using direct contact with the nerve, rather than indirect sensing (via a muscle coupled to a nerve)" is incorrect because the Board "did not state what claim 4 requires, or is interpreted to require." A11 quoting A1290. *Third*, while not disputing that the broadest reasonable interpretation of claim 4 "includes sensing a response of a nerve by monitoring an [EMG] response of a muscle coupled to a nerve," "NuVasive's arguments are pertinent to issues of the scope of claim 4 and whether there is written descriptive support for claim 10." A11-12. Those arguments do not answer whether claim 10 is broader than claim 4, which requires determining whether claim 10 encompasses any subject matter that claim 4 does not. *Id.*. *Fourth*, "[t]he record indicates that there are various reasons why the scope of claim 10 is not merely just a subset of [claim 4]." A12. Involuntary muscle spasm and voluntary muscle movement may cause an EMG response of a muscle, and a depolarized nerve does not necessarily result in a measurable EMG response in the muscle. *Id.* Judge Song concluded:

> [W]hereas claim 4 would not encompass such non-nerve related causes for EMG responses of the muscle, the language of new claim 10 would encompass such response so as to be broader than claim 4 in this respect.

Noting that "NuVasive does not disagree or factually challenge" that these non-nerve EMG responses exist, but argues that they are not within the scope of claim 10, Judge Song pointed out that "this argument relies on limitations not appearing in claim 10." A13-14. The only requirement in claim 10 is that a muscle is coupled to a nerve that is depolarized by stimulation. *Id.* Thus, the sensed EMG response need only be "of a muscle" that happens to be coupled to a depolarized nerve, it "does not require the sensed EMG response of the muscle to be *caused by* the depolarized nerved coupled [to it]." A14.

### B. Medtronic's Proposed Obviousness Rejections Based on the Koros Patent

#### 1. Medtronic Argued the Koros Patent Teaches Retractor Blades with Locking Members That Secure the Assembly during Surgery

After NuVasive added new claims 10-65, Medtronic proposed grounds of rejection that relied, in part, on the Koros patent. A323,350-52. Although cited during prosecution of the '058 patent, the Koros patent was not considered regarding features added in NuVasive's new claims. *See also* 35 U.S.C. §303(a) ("The existence of a substantial new question of patentability is not precluded by the fact that a patent or

printed publication was previously cited by or to the Office or considered by the Office.").

NuVasive's new claims 10-29 and 33-36 include, among other features, a "locking member" "within a passageway of the first retractor blade."[3] A230-31,234-35. Medtronic argued that this feature is obvious in light of the Koros patent, including Figures 1, 2 and 5. A314; A383-84; A362. Specifically, fixation screws (83) were cited as corresponding to the claimed locking member. A383-84; A362. Figure 1 of the Koros patent, titled in part a "retractor/distractor system," is reproduced below. A1058,1066 (Koros) (col.5:27-29). The distractor (32) and retractor (30) blades are highlighted.[4]

[3] Claims 10-29 include that the locking member is "releasably received." Claim 33 does not include "releasably received," but that is not relevant to this appeal.

[4] Explanatory labels from the patent are added to the figures in this brief.

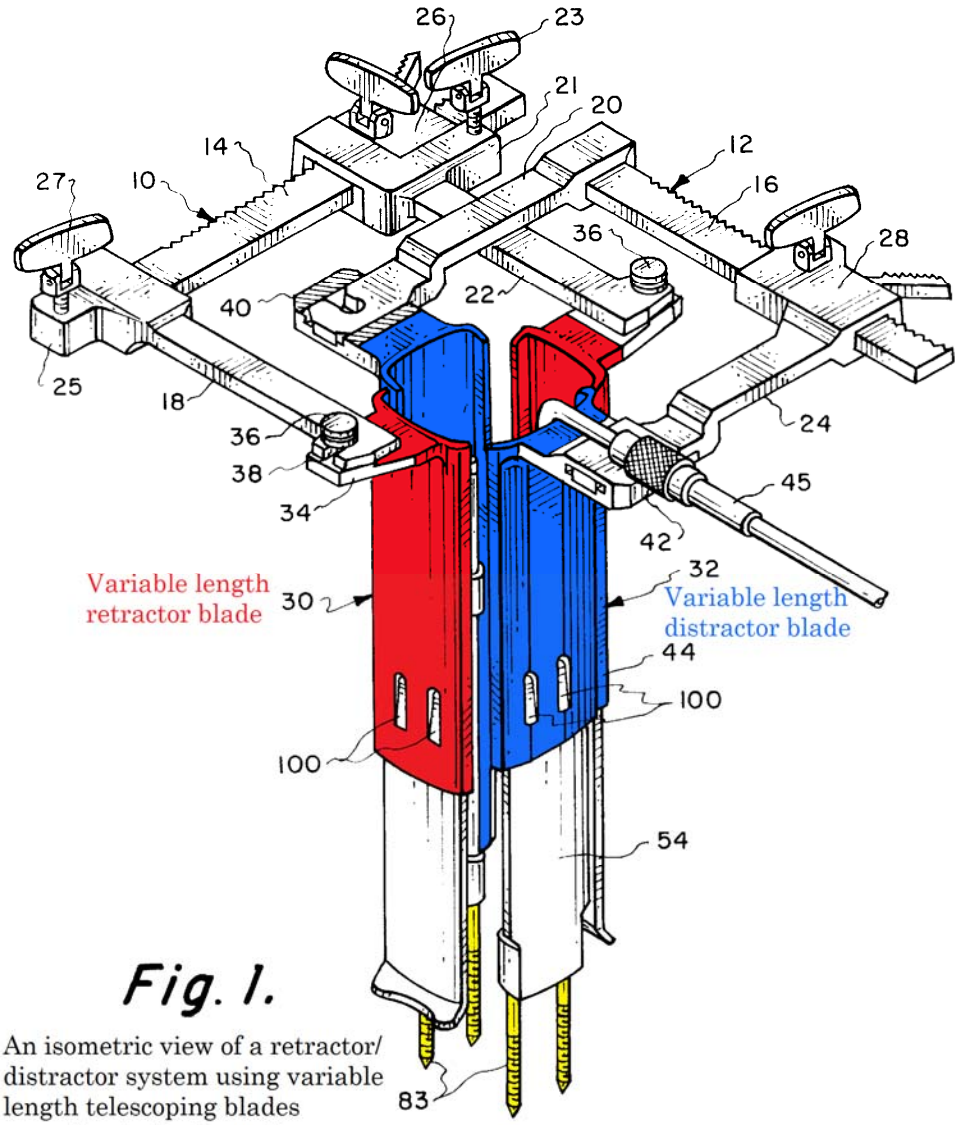


*Fig. 1.*

An isometric view of a retractor/distractor system using variable length telescoping blades according to the invention.

Figure 5 of the Koros patent shows a sectional view of its retractor/distractor system in place during surgery. A1061. Though the blades are labeled "distractor," (32) the patent describes fixation screws (83) that "pass through blades of the *retractor* and are fastened to adjacent vertebra." A1064 (Koros) (co.1:49-51).

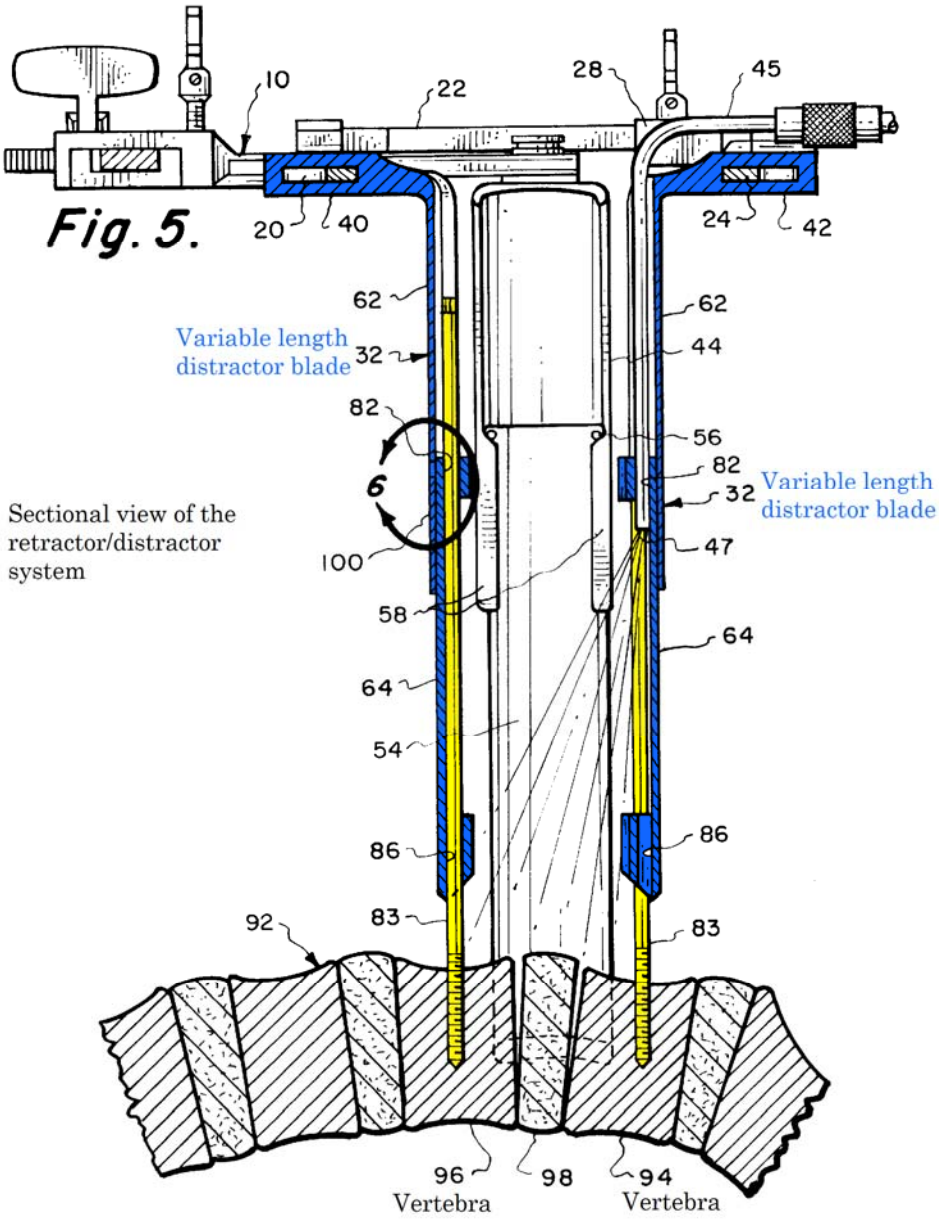


Figure 8 of the '058 patent (below) shows a pair of retraction blades (90 and 92) that "expand[] and/or modify the distraction corridor to establish and maintain an operative corridor to the surgical target site." A67 (Miles) (col.8:17-22). Figures 9 and 11 are the retractor blade and locking member for use with the retractor blade, respectively. A39,41.

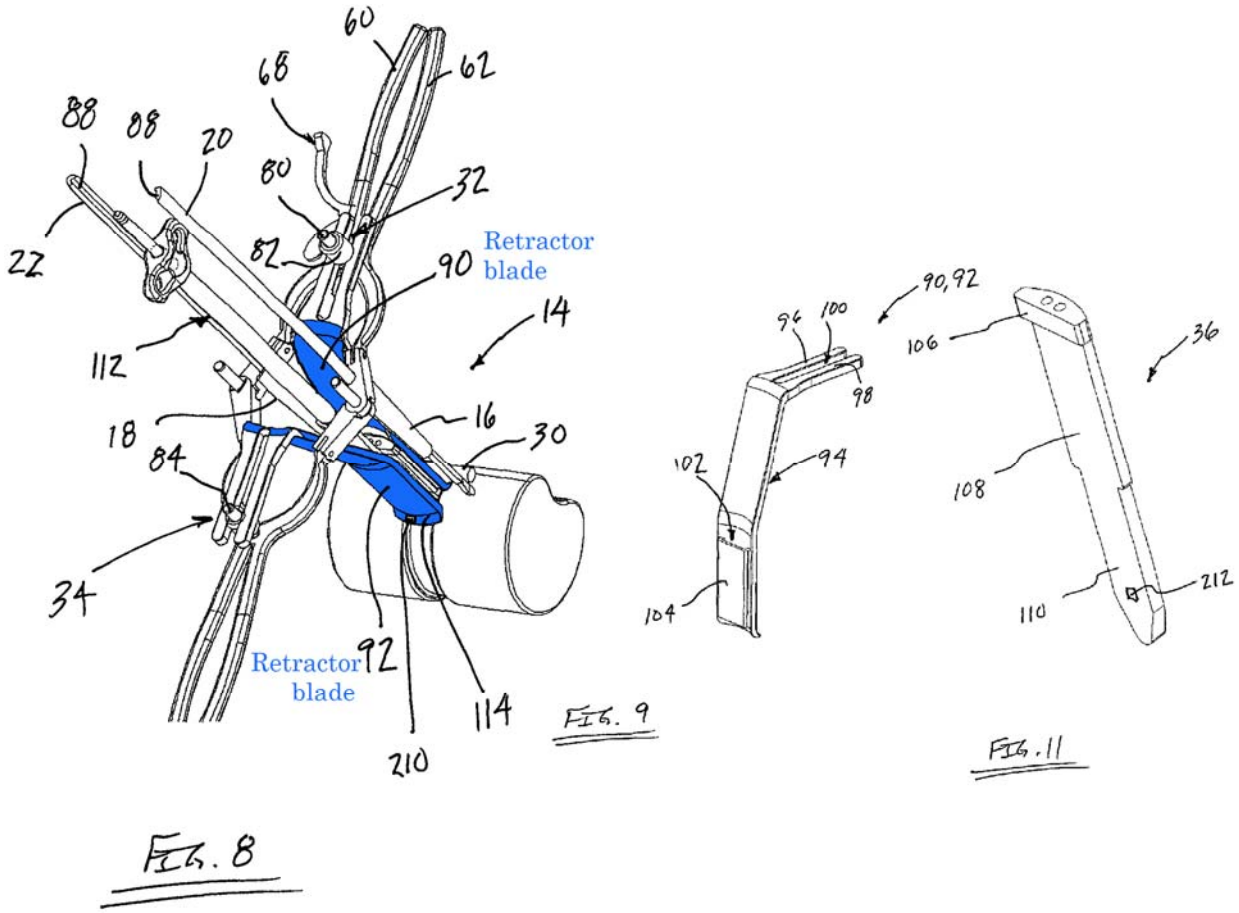


FIG. 8

FIG. 9

FIG. 11

The '058 patent describes the locking member of Figure 11 extending through the passageway of the retractor blade (102 of Figure 9) so the distal region of the locking member (110) secures the retractor blades during use. A67 (Miles) (col.8:31-43).

### 2. The PTAB Rejected Medtronic's Proposed Obviousness Rejection with Respect to Claim 10, but Adopted It With Respect to Claim 33

Medtronic proposed similar grounds of rejection for claims 10 and 33 in that both recite locking members and Medtronic relied upon screws

(83) of the Koros patent to teach that feature for each claim. A370-76; A391-95; A1521-25. While the PTAB adopted the locking member argument for claim 33, it did not adopt the same argument for claim 10. A1264-68. As discussed, NuVasive cancelled claim 33 before requesting rehearing of the broadening rejection of claim 10. A1275-81.

That the Koros patent's fixation screws are locking members received within a passageway of a blade is not disputed. There is also no dispute that Koros's fixation screws extend through passageways and fasten to vertebrae to keep the apparatus from moving during surgery. A1057,1064 (Koros) (col.1:11-15,48-51). What was and is in dispute with respect to claim 10 is whether the fixation screws pass through the blades of a retractor, as Medtronic argues. For reasons that are not clear, this issue was not disputed with respect to claim 33.

During appeal to the Board, after cancelling claim 33, NuVasive countered, and the PTAB agreed with respect to claims 10-29, that Koros's fixation screws are not received within a retractor blade, as the '058 patent requires, because they are not inserted through the blade labeled "retractor"—blade 30—and are instead inserted through a blade labeled "distractor"—blade 32, a "different structure" according to

NuVasive. A1138, A1265-1268 (numbers refer to designations in the Koros patent). Medtronic countered that the "different structure" is a retractor blade because Koros discloses various retractor blades, including "blade 32." A1147,1165; A1066 (Koros) (col.6:45). That the Koros patent assigns one blade a reference number of 30 and another 32 is irrelevant to whether the document, viewed in its entirety, shows a locking member (screw 83) being inserted through a passageway (passage 86) in a retractor blade (30 and 32). A1057-68 (Koros); A1147,1165-66. As can be seen from Figures 2-3 of the Koros patent, blades 30 and 32 are structurally similar, albeit with different extension members attached (54 and 64). A1059.

The PTAB agreed with Medtronic that the screws 83 are "locking members" as required by claim 10; but concluded it was "not evident how those members are 'received within a passageway of the first retractor blade'" as claim 10 requires. A1266. According to the Board, the Koros patent's passageways are associated with "distractor blades 32 and not the separate retractor blades 30." *Id.*

### 3. On Rehearing, the PTAB Maintained Its Refusal to Apply Medtronic's Proposed Rejection

#### a. Medtronic Argued the Koros Patent Describes Blades That Function as Retractors, Regardless of Nomenclature; and "Distractor" Blades Are So-Called Because They Distract Bone

In its request for rehearing Medtronic reiterated that the Koros patent is directed to locking members that extend through retractor blades, regardless of whether they sometimes are referred to as distractor blades. A1294-1304,1298.

In support, Medtronic noted the Koros patent describes the invention as "relat[ing] to retractors used in surgical procedures and more particularly relat[ing] to a retractor for lumbar spinal fusion that includes adjustable length retractor blades and guides for positioning fixation screws." *Id.*; A1064 (col.1:11-14). It argued the blades labeled "distractor" in Koros function as retractors. For example, the Koros patent states "a pair of retractor frames known as retractor and distractor are provided" and "[w]ith two retractor frames (i.e., a retractor and distractor) the retractor blades surround the surgical site providing a clear view to the surgeon." A1064 (Koros) (col.2:65-67), 1065 (col.3:1-3,4:62-67).

Medtronic maintained that the "distractor" blades are so-called because they perform the additional function of distracting bone. A001297. As evidence, Medtronic noted that the fixation screws secure the blades to adjacent vertebra (bone), which "allow[s] adjacent vertebrae to be spread by the distractor." A1064-65,1067 (Koros) (col.1:48-51,2:66-3:1, 4:49-55, 7:15-18. Spreading adjacent vertebrae in this manner is often referred to as "distracting." A967,987 (Michelson) (col.9:36-40) ("*distract* the disc space D and align the adjacent vertebrae … by urging them apart")).

Medtronic concluded that a POSA, reading the Koros patent in its entirety, is taught that the "distractor" blades retract tissue and distract bone, rendering NuVasive's "locking member releasably received within a passageway of the first retractor blade" obvious.

### b. Medtronic's Citation to "Retractor Blades 30" In Its Claim Charts Was Emphasized by The Board

In opposition to Medtronic's requested rehearing, NuVasive emphasized that Medtronic did not originally contend that the blades 32 would serve as retractor blades. A1485,1488-89. The Board emphasized this same point when again refusing to apply Medtronic's proposed rejection, "Medtronic directed our attention to 'retractor blades 30'" (in

the claim charts provided during reexamination) and while "Koros discloses two sets of 'blades'" and "associates its screws 83 with distractor blades 32," they were "not persuaded that Koros contemplated the use of its screws 83 with retractor blades 30." A17-18,20. It was not disputed that Medtronic relied upon screws 83 in its claim charts with respect to the locking member feature.

## Summary of Argument

### I. NuVasive Impermissibly Broadened Original Claim 4

The strict statutory prohibition against broadening claims during reexamination employs an infringement-based test: if the amended claim can be infringed by any conceivable process that would not have infringed the original claim, then the amended claim is broader. The PTAB here failed to apply this test, which compels the conclusion that NuVasive impermissibly broadened the '058 patent's claims.

NuVasive broadened its claims by changing the step of "sensing a response of a nerve depolarized by said stimulation" (original claim 4) to "sensing an [] EMG response of a muscle coupled to a nerve depolarized by said stimulation" (amended claim 10). But a muscle generates EMG responses from sources other than just depolarization of a particular nerve. Thus, there are conceivable processes that would infringe claim 10 that would not infringe claim 4, and claim 10 is broader than claim 4.

The PTAB majority erred in finding claim 10 narrower than claim 4 for at least five reasons.

First, instead of applying the correct test for broadening, the PTAB relied on the presence of support for claim 10 in the specification to conclude that it was not improperly broadened. But the mere presence of

support in the specification does not determine whether claims have been broadened. That determination turns on the well-established infringement-based test of this Court's precedent. The specification may disclose more than the inventor claims; hence the long-standing rule that unclaimed disclosures in the specification are dedicated to the public. The PTAB's decision would vitiate this disclosure-disclaimer rule.

Second, the PTAB erred by importing limitations from the specification to narrow claim 10. The Board concluded that claim 10 excludes any EMG response of a muscle that is not the result of stimulating the nerve coupled to it during surgery. But claim 10 has no such limitation. It is well settled that claim construction must focus on language of the claims, and not import limitations from the specification. Claim 10 does not require that the sensed EMG response of the muscle be *caused* by the depolarization of that particular nerve, only that the muscle is coupled to that nerve. The specification acknowledges that measured EMG activity in a muscle can have numerous causes, not just depolarization of the associated nerve by electrical stimulation.

Third, the PTAB violated the rule that requires claims in reexamination to be given their broadest reasonable interpretation. The

plain language of claim 10 does not exclude non-nerve sources of EMG responses, and covers responses that result from other sources. Yet the PTAB imported a limitation from the specification to exclude those sources.

Fourth, the PTAB credited the applicant's intent, rather than what was claimed. Claims are to be read as written, not redrafted by the courts or the PTAB. The PTAB's analysis incorrectly considered what NuVasive said it intended to claim, not what it did claim, and led the Board to construe "sensing an electromyographic (EMG) response of a muscle coupled to a nerve" to exclude EMG responses arising from causes other than the coupled nerve. Particularly because NuVasive declined the opportunity during reexamination to submit clarifying amendments, the Board erred in effectively redrafting claim 10.

Fifth, the PTAB's construction of claim 10 leads to an indefinite infringement analysis. An EMG response of a muscle may result from stimulating the nerve coupled to it or from other causes that the Board found are outside the scope of claim 10. But a known problem in the art is distinguishing between the causes of recorded EMG responses. The '058 patent does not solve this known problem. Thus, under the Board's

construction requiring distinctions between causes of the EMG response, infringement determinations would be impermissibly uncertain and inexact.

## II. NuVasive's Amended Claims are Obviousness in Light of the Koros Patent

A claim is obvious if the differences between it and the prior art would have been obvious to a POSA when the invention was made. The prior art is examined in its entirety, and the POSA is presumed to know all of the prior art.

During reexamination NuVasive added the limitation of a "locking member" "within a passageway of the first retractor blade." This feature is obvious in light of the Koros patent, which shows a locking member on what the Koros patent calls "distractor" blades.

To begin, the Board improperly relied on the naming convention in the Koros patent, not on what that reference in its entirety taught a POSA. The Koros patent's "distractor" blades are so-named because they distract/retract bone in addition to retracting soft tissue like NuVasive's so-called retractor blades. The Koros patent includes a locking mechanism on its so-called "distractor" blades, which function as retractor blades.

Having incorrectly relied on the Koros patent's naming convention, the Board then settled on the position that Medtronic's original claim charts referred to blades 30 when the locking members (screws 83) were on blades 32. This, however, ignores that these claim charts indisputably relied upon "fixation screws (83)"—and neither NuVasive nor the Board argued that the particular blade on which a locking member is positioned leads to a patentable distinction.

The Board's improperly limited analysis avoided the real question of whether the locking member limitation of claim 10 is obvious in light of the Koros patent (or why it adopted that very position for claim 33 but not for claim 10). See pages 32-33 supra.

## Argument

### I. The Standard of Review

This Court reviews de novo the PTAB's ultimate determination that claim 10 was not impermissibly broadened or unpatentable as obvious. *Creo Prods., Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1344 (Fed. Cir. 2002) ; *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). The Board's underlying factual determinations are reviewed for whether there is substantial evidence to support them. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1342-43 (Fed. Cir. 2008). The Board construes claims to give them the broadest reasonable interpretation in light of the specification of the patent in which they appear. *In re Yamamoto*, 740 F.2d 1569, 1572 (Fed. Cir. 1984), 37 C.F.R. 42.100(b). This Court reviews the Board's claim construction de novo, without deference. *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014).

### II. Claim 10 Was Broadened During Reexamination

Because it applied the wrong test, used the wrong claim construction, and conducted an analysis that is contrary to the rationale for the strict prohibition against broadening, the PTAB concluded in error that claim 10 was not improperly broadened.

### A. There is a Strict Statutory Prohibition against Broadening Claims on Reexamination

Reexamination assesses existing claims in light of newly discovered prior art or new interpretations of "old" art. *In re Swanson*, 540 F.3d 1368, 1375-1376 (Fed. Cir. 2008). Claims may be amended during reexamination, but there is a statutory prohibition against broadening claims, which this Court has strictly upheld. 35 U.S.C. §314(a); *Senju Pharm. Co. v. Apotex, Inc.*, 746 F.3d 1344, 1352 (Fed. Cir. 2014).

### B. The Test for Broadening Is Whether an Amended Claim Can Be Infringed By Any Conceivable Process That Would Not Have Infringed the Original Claim

The test to determine whether a claim is broadened was outlined by Examiner-in-Chief P.J. Federico in the context of reissue practice, following adoption of the Patent Act of 1952:

> [I]f a claim of a reissue can hold something as an infringement which would not be an infringement of any of the claims of the original patent … then the particular claim of the reissue enlarges the scope of the claims of the original patent, and that a claim is broadened if it is broadened in any respect. P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. §1 (West 1954), *reprinted in* 75 J. Pat. & Trademark Off. Soc'y 161, 204-5 (1993).

This Court applies the same standards on broadening in both the reissue and reexamination contexts. *Anderson v. International Eng'g & Mfg. Inc.*, 160 F.3d 1345, 1349 (Fed. Cir. 1998) ("In determining whether the scope of a claim has been enlarged, the reexamination practice has shared a body of precedent developed for reissue determinations.").

Thus, this Court has consistently used the simple, infringement-based test set forth above to determine whether a claim in reexamination has been broadened. Succinctly stated, a new claim is broader if it "contains within its scope any conceivable apparatus or process which would not have infringed the original patent." *In re Freeman*, 30 F.3d at 1464; *see also Tillotson*, 831 F.2d at 1037 n.2; *In re Ruth*, 278 F.2d 729, 730 (C.C.P.A. 1960); *In re Rogoff*, 261 F.2d 601, 603 (C.C.P.A. 1958).

During reexamination, when determining claim scope, the PTO must give claims "their broadest reasonable construction consistent with the specification." *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (citing cases). Thus, here, to comply with the statutory requirements for reexamination outlined in 35 U.S.C. §314(a), the scope of claim 10 must be the same or narrower than the scope of original claim 4, when both claims are given their broadest reasonable interpretation.

### C. There Is No Dispute That a Muscle [Claim 10] Can Generate an EMG Response, Without Responding To a Nerve Depolarized By Stimulation [Claim 4]

Only the sensing limitations of original claim 4 and amended claim 10 are at issue here. Claim 4 recites "sensing a response of a nerve depolarized by said stimulation," while claim 10 recites "sensing an EMG response of a muscle coupled to a nerve depolarized by said stimulation". A228-231.

There is no dispute that an EMG response of a muscle can result from causes other than a nerve depolarized by "said stimulation," and that depolarization of a nerve will not always result in EMG activity in the muscle coupled thereto. Examples of unrelated causes of EMG responses include muscle movement, either voluntary or involuntary; and a nerve signal from a different level of the spine—one that is not stimulated during surgery. A1449,1462-64 (Prass) (col.1:66-2:3, 4:1-5, 5:23-45); A793,940 (col.2:13-22) (Epoch); A1069,1096-97 (Finneran) (col.5:17-24, 7:32-44). Because such EMG responses of a muscle would infringe claim 10, but not claim 4, claim 10 is broader.

NuVasive inverted the analysis and argued that sensing an EMG response of a muscle is one way of sensing a response of a nerve, such

that claim 4 "includes within its scope sensing a response of a muscle coupled to a nerve" and is broader than claim 10. But the question is not whether sensing a response of a muscle is encompassed by claim 4. The question is whether claim 10 can be infringed by any conceivable process which would not have infringed claim 4. *In re Freeman*, 30 F.3d at 1464. Importantly, claim 10 does not require that the EMG response be *caused by* the nerve depolarized by said stimulation, only that the muscle that produces the EMG response is *coupled to* a nerve depolarized by said stimulation. That a muscle that happens to be coupled to a nerve can produce an EMG response due to causes other than a nerve depolarized by "said stimulation" means claim 10 is invalid because it is broader than claim 4.

### D. For At Least Five Reasons, the PTAB Erred In Finding Claim 10 Narrower Than Claim 4

By construing claim 10 to exclude the known causes of an EMG response of a muscle discussed above in section IV.A.3, the PTAB concluded in error that claim 10 is narrower than claim 4. This was wrong for at least five reasons.

### 1. First, the PTAB Erred Because the Presence of Support in the Specification Does Not Permit Broadening of Claims in Reexamination

Both the PTAB and NuVasive improperly relied on the '058 patent specification to conclude that claim 10 is narrower than claim 4.

In concluding that claim 10 is not broader than claim 4, the Board relied upon support in the '058 patent specification for claim 10's "sensing a response of a muscle coupled to a nerve." Specifically, the Board noted that the specification refers to sensing EMG responses of muscles as a way of detecting nerve activity. A24. But this reliance on the specification is misplaced for at least two reasons.

First, while the written description requirement mandates support for a claim in the specification, whether that requirement is met does not determine whether a claim has been broadened. The specification may disclose more than the inventor chooses to claim, but such disclosure does not allow an inventor to later broaden the claims. Hence, the long-standing rule that unclaimed disclosures in the specification are deemed dedicated to the public. *Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 352 (1881). Here, the PTAB's analysis vitiates the disclosure-disclaimer rule and the prohibition against broadening claims during reexamination by

allowing claims to be broadened if they are supported by the specification.

Second, unlike the complete prohibition on broadening claims in reexamination, claims may be broadened in reissue proceedings within two years of patent issuance, but only if the broadened claim is supported by the specification. (See 35 U.S.C. §251 requiring that "the invention [was] disclosed in the original patent"). But here the Board's conclusion that claim 10's "sensing a response of a muscle coupled to a nerve" limitation has support in the specification is irrelevant to whether claim 10 is broader than claim 4, since claims may not be broadened on reexamination, whether supported or not.

NuVasive relied on the specification as support for its conclusion that claim 4 encompasses sensing an EMG response of a muscle, as recited in claim 10. A1283-91. But whether or not claim 4 could be interpreted to cover sensing an EMG response is irrelevant. The relevant question, applying this Court's well-established infringement-based inquiry, is whether claim 10 can be infringed in ways that claim 4 cannot. *In re Freeman*, 30 F.3d at 1464. The answer is yes, claim 10 can

be infringed in ways claim 4 cannot, for the reasons explained above in section IV.A.1.

### 2. Second, the PTAB Erred By Improperly Importing Limitations to Narrow Claim 10

The analytical focus of claim construction "must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'". *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1354-55 (Fed. Cir. 2014); quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). It is equally well-settled that claim limitations cannot be imported from the specification into the claims. *McCarty v. Lehigh Val. R. Co.*, 160 U.S. 110, 116 (1895) ("The difficulty is that, if we once begin to include elements not mentioned in the claim, in order to limit such claim … we should never know where to stop.").

The PTAB construed claim 10 to exclude any EMG response that is not the result of stimulating the nerve coupled to it during surgery. Claim 10 has no such limitation. Claim 10 explicitly recites that what is sensed is "an [EMG] response of a muscle coupled to a nerve depolarized by said stimulation." As Judge Song pointed out, this limitation "does

not require the sensed EMG response of the muscle to be *caused by* the depolarized nerved coupled thereto." A14. It only requires that the EMG response is of a muscle coupled to a nerve depolarized by stimulation. *Id.*

While the '058 patent specification discloses embodiments where the EMG response of a muscle is caused by a nerve depolarized by stimulation during surgery, as explained above, it is improper to import limitations that are not found in the claims. *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 792 (Fed. Cir. 2010) ("A construing court's reliance on the specification must not go so far as to import limitations into the claims from examples or embodiments appearing only in the patent's written description unless the specification makes clear that the patentee intends for the claims and the embodiments in the specification to be strictly coextensive." (internal quotation marks omitted).). *See also, Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (Although claim interpretation "may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim.").

Here, the plain meaning of the language of claim 10 does not exclude the EMG responses of a muscle caused by, for example,

involuntary or voluntary muscle movement, as the PTAB found. NuVasive did not act as its own lexicographer—clearly setting forth a definition to support the PTAB's conclusion that such responses were excluded. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999)). To the contrary, the '058 patent specification acknowledges that measured EMG activity in a muscle can have numerous causes other than depolarization of the associated nerve by electrical stimulation. *See e.g.* '058 patent 4:15-17, 9:58-60 (EMG activity in a muscle "may" indicate stimulation of the associated nerve.). Particularly, since reexamination allows claims to be clarified and narrowed, it is improper and unnecessary to import narrowing limitations from the specification into the claim—especially when the narrow scope is not supported by the language of the claim.

### 3. Third, the PTAB Erred By Failing to Give the Amended Claims Their Broadest Reasonable Interpretation

It is well-settled that claims in reexamination are to be given their broadest reasonable interpretation. *In re Yamamoto*, 740 F.2d at 1572. The PTAB violated this rule with respect to claim 10. As explained above, claim 10 does not exclude non-nerve sources of EMG responses. And even if sensing an EMG response of a muscle is one way to

determine whether the coupled nerve depolarized, using the broadest reasonable interpretation, claim 10 also covers responses that result from other sources. As this Court has noted, it is proper to construe claims broadly during reexamination because the patentee may amend the claims to obtain more precise claim coverage. *Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d at 1364. The Board's failure to apply this rule here was error which led to its incorrect conclusion that claim 10 is not broader than claim 4.

#### 4. Fourth, the PTAB Erred by Crediting the Inventor's Purported Intent, Instead Of What Was Claimed

Claims are to be read as they are written, and cannot be redrafted by the courts or the PTAB. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1344 (Fed. Cir. 2009); see also *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1563 (Fed. Cir. 1995) (Plager, J., concurring) ("[The court] is not free to read the claims as they might have been drafted, even if as drafted they do not accomplish what the inventor may have intended."). The PTAB's analysis incorrectly considered what NuVasive said it intended to claim, not what it actually claimed, and led to the Board construing "sensing a response of a muscle coupled to a nerve" to exclude EMG responses arising from causes other than the coupled

nerve. The Board's construction includes an extraneous limitation, imported from the specification but not required by the plain language of the claim.

Also, after the Board initially determined claim 10 was impermissibly broadened, its rejection was entered as a New Ground. A15 at FN4, A001226-74. This gave NuVasive the opportunity to reopen prosecution and submit clarifying amendments to claim 10. *Id.*, *see also* MPEP §1214.04. But NuVasive chose not to take that opportunity. Particularly, since NuVasive failed to clarify its claim, the Board should have declined NuVasive's invitation to re-draft the claim and read in a narrowing limitation.

### 5. Fifth, the PTAB's Construction of Claim 10 Leads to Improperly Indefinite Infringement Analyses

Finally, the PTAB's construction of claim 10 was error because it renders uncertain whether particular embodiments infringe. As explained above, an EMG response of a muscle may result from stimulating the nerve coupled to it and may also result from other causes found by the Board to be outside the scope of claim 10. However, a known problem in the art is distinguishing between the causes of recorded EMG responses. A1343,1366 (Kelleher) (ll.18-20). And,

although an EMG response may result from a combination of sources, the PTAB's construction of claim 10 requires distinguishing between those sources, but offers no instruction on how to distinguish the various sources of an EMG response. Thus, under the Board's construction, infringement determinations would be improperly unclear and inexact. 35 U.S.C. §112 ¶2.

## III. The Koros Patent Renders NuVasive's Additional Limitation Obvious

Obviousness under 35 U.S.C. §103 is a question of law based on underlying factual inquiries set out in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). These inquiries include examining the scope and content of the prior art and determining the differences between the claims and the prior art. It is well-settled that the prior art reference must be considered in its entirety and the obviousness analysis must include a "full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d at 241; ("[E]ach prior art reference must be evaluated as an entirety, and ... all of the prior art must be evaluated as whole.") *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1093-94 (Fed. Cir. 1985), vacated & remanded, 475 U.S. 809 (1986), on remand, 810 F.2d 1561 (Fed. Cir. 1987), cert. denied, 481 U.S.

1052 (1987); *Ex parte Raychem Corp.*, 17 USPQ2d 1417, 1422 (B.P.A.I. 1990) ("a prior art reference must be considered in its entirety."). Also, the POSA is presumed to know all of the prior art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (POSA "is presumed to be aware of all the pertinent prior art.").

### A. Viewed in its Entirety, the Koros Patent Renders Obvious a Locking Member Releasably Received Within a Passageway of a Retractor Blade

During reexamination NuVasive added the limitation of a "locking member releasably received within a passageway of the first retractor blade." A231-235. At issue here is whether the Board erred in finding this limitation non-obvious in view of the prior art Koros patent. Viewing the Koros patent in its entirety, the Board's non-obviousness conclusion plainly was incorrect. While Medtronic asserted that claims 10-16 and 19-27 should be rejected in view of the Koros patent in further view of Marino, Mathews, Michelson, Kelleher, Finneran, Foley and others, the only feature asserted to be missing from the prior art is the locking member. A349-353,357-358.

### 1. The PTAB Erred in Its Factual Finding That Medtronic Did Not Refer to the Koros Patent's Retractor Blades

As shown above on pages 30 and 31, Figures 1 and 5 of the Koros patent show "fixation screws" (83)—a locking member—on so-called "distractor blades 32." The blades labeled "retractor blades 30" in the Koros patent are structurally similar to blades 32, but do not include screws 83. Screws 83 screw into the vertebrae, which are aligned with blades 32 in the figures, rather than blades 30.

The PTAB concluded that the "locking member releasably received within a passageway of the first retractor blade" was not obvious in light of the Koros patent by mischaracterizing Medtronic's argument. Medtronic maintained that the distractor blades function as retractor blades and render the locking member limitation of claim 10 obvious. The PTAB, however, focused on whether the words "distractor blades 32" appeared in Medtronic's initial claim chart. For example, the PTAB stated "with respect to claim 10, the [Medtronic claim] chart makes no mention of Koros's 'distractor blades 32,'" and "the blades relied on are 'retractor blades 30." A21-23. Though the Board is correct that the words "distractor blade 32" are not in Medtronic's claim charts, it is not in dispute that Medtronic relied upon fixation screws 83 (which are on

blades 32), and cited to Figures 1 and 5 of the Koros patent. A1297-1301; A362,274; A384,395; A1153-54,1164. These figures (shown above at pages 30 and 32) include blades 30 and 32 and screws 83, which screws act as locking members. The Board's refusal to consider Medtronic's arguments regarding blade 32 was error.

### 2. The PTAB Erred by Failing to Consider the Koros Patent in Its Entirety, Which Teaches the Retractor Blades of NuVasive's Claim 10

The Board reached its non-obviousness conclusion by looking only at whether Medtronic referred to Koros's "distractor" blades, which include the locking member, and focusing on the fact that Koros's so-called retractor blades lack a locking member. In doing so, the Board erred by failing to take into account the full scope of the Koros patent.

#### a. The Koros Patent Concerns Retractor Assemblies

The Koros patent is directed not to distractors, but rather to "retractors used in surgical procedures and more particularly relates to a retractor for lumbar spinal fusion that includes adjustable length retractor blades and guides for positioning fixation screws." A1064 (Koros) (col.1:11-14). Its locking members (fixation screws (83)) extend through passageways of blades that function as retractors. Despite this,

the Board maintained that the passageways are not associated with a "retractor" blade, because the Koros patent calls the blades that include locking members—"blades 32"—distractor blades. A20 But viewing the Koros patent in its entirety clarifies that Koros's "blades 32" perform the same function as NuVasive's "retractor blades" by retracting tissue. A1057-68 (Koros).

Also, although they are labeled "distractor" in Figures 1 and 5, the Koros patent elsewhere and repeatedly refers to these blades as retractor blades. For example, an important feature of Koros's retractor is to remain in place during surgery, a goal achieved by "fixation screws [that] are provided that pass through the blades of the *retractor*." A1064 (Koros) (col.1:48-51). The Koros patent also:

- states that the object of the "invention is to provide a retractor with an [sic] adjustable length blades having guides for fixation screws" *Id.* (col.2:19-22);
- discusses features that may be used with "retractor blades" (line 25) and that such feature may be used with "any retractor" (line 23) A1064-1065 (col.2:34-36,3:19-55);

- contains a preferred embodiment that includes "blades [that] include tubular guides for fixation screws," A1065 (col.3:49-53), and those tubular passageways are provided "in the upper and lower ends of the variable retractor blade extension" *Id.*;
- shows in Figure 3 only "distractor" blade 32, which is described as a "view of a second embodiment of a *retractor* variable length blade including tubular guides for mounting a plurality of fixation screws…" A1059,1066 (col.5:32-34); and
- shows that blades 30 and 32 are structurally similar and, as shown in Figures 2 and 3, are simply provided with different extensions (54 and 64) A1059; and
- shows in the depicted embodiment in Figure 1, the extension member with the locking member (screws 83) is received on blade 32. A1058.

Given these disclosures of the Koros patent, the Board's focus on whether Medtronic referred to "distractor blades 32" in its original claim chart was misplaced. The Board incorrectly ignored that Medtronic's claim chart identified fixation screws (83) as the locking member—neither the Board nor NuVasive asserted that the identified fixation

screws are not locking members. A362,274; A384,395; A1153-54,1164. Further, neither the Board nor NuVasive argued that the particular blade on which a locking member is positioned leads to a patentable distinction. This issue is exacerbated by the Board's decision to find claim 33 unpatentable based on the same manner of applying Koros that it rejected for claim 10.

#### b. The "Distractor" Blades are So-Named Because They Distract/Retract Bone, But Also Retract Soft Tissue

There are two reasons why the blades 32 are labeled "distractor." First, this label distinguishes from "retractor" blades 30. Second, blades 32 are so labeled because they retract tissue and also perform the additional function of distracting bone. The fixation screws secure the blades 32 to adjacent vertebrae to prevent the blades from moving during surgery (A1064 (Koros) (col.1:48-51), Fig. 5 A1061); and "allow adjacent vertebrae to be spread by the distractor" (A1064-1065,1067 (Koros) (col.2:66-3:1, 4:49-55, 7:15-18). Vertebral "distraction" allows the surgeon to efficiently operate on the affected area, often the disc between vertebrae. (A1067 (Koros) (col.7:44-47); A967,987 (Michelson) (col.9:36-40). Thus, although the "distractor" blades are so-labeled because they

distract/retract bone, they also retract soft tissue, and thus teach the retractor element of NuVasive's claim.

## Conclusion and Statement of Relief Sought

For the foregoing reasons, the PTAB's decisions should be reversed.

October 20, 2014

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# Addendum

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.
Requester

v.

NUVASIVE, INC.
Patent Owner

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Appeal 2012-009491
Reexamination Control 95/001,247
Patent 7,582,058
Technology Center 3900

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Before JEFFREY B. ROBERTSON, DANIEL S. SONG, and JOSIAH C. COCKS, *Administrative Patent Judges*.

Opinion of the Board filed by COCKS, *Administrative Patent Judge*.

Opinion Dissenting filed by SONG, *Administrative Patent Judge*.

DECISION ON PATENT OWNER'S
REQUEST FOR REHEARING

## I. INTRODUCTION

Patent Owner, NuVasive, Inc. ("NuVasive"), requests rehearing of the Decision mailed March 18, 2013 ("Decision").[1] Third Party Requester, Medtronic, Inc. ("Medtronic") has filed comments in response to Nuvasive's Request.[2]

In the Decision, we reversed the Examiner's determination not to enter a proposed ground of rejection of claims 10-50 of U.S. Patent 7,582,058 (the "'058 patent") under 35 U.S.C. § 314(a), and, in doing so, entered the rejection by operation of 37 C.F.R. § 41.77(b). Decision 8-11. NuVasive requests that the Board withdraw the rejection as applied to claims 10-16 and 19-27. PO Rh'g Req. 1.

We have considered NuVasive's request and modify our decision in the manner discussed below. NuVasive's Request for Rehearing is *granted*.

## II. DISCUSSION

A "request for rehearing must state with particularity the points believed to have been misapprehended or overlooked in rendering the Board's opinion reflecting its decision." 37 C.F.R. § 41.79(b)(1). Here, NuVasive contends that the Board misapprehended or overlooked the broadest reasonable interpretation of the scope of claim 10 in concluding

[1] *See* NuVasive's "Request for Rehearing Under 37 C.F.R. § 41.79" filed April 18, 2013 ("PO Rh'g Req.").

[2] *See* Medtronic's "Comments in Opposition to Request for Rehearing" filed May 20, 2013 ("3PR Comm.").

that it was improperly broadened vis-à-vis claim 4 so as to violate of 35 U.S.C. § 314.

Original claim 4 of the '058 patent is directed to a method of accessing a surgical target site and includes a step of "sensing a response of a nerve depolarized" by electrical stimulation. '058 patent, col. 18, ll. 31-32. Claim 10 was added by amendment during reexamination and, in lieu of the above-noted sensing step, instead recites "sensing an electromyographic (EMG) response of a muscle coupled to a nerve depolarized" by electrical stimulation. App. Br. Claims App'x. In the Decision, we concluded that the record did not establish that the muscle sensing step recited in claim 10 is simply a narrower statement of the nerve sensing step that was recited in claim 4.

*A. NuVasive's Position on Rehearing*

NuVasive contends that the Board overlooked or misapprehended certain aspects of the claim that, when construed in light of the disclosure of the '058 patent, undermine the Board's conclusion that above-noted sensing step in claim 10 constitutes impermissible broadening vis-à-vis the sensing step of claim 4. PO Rh'g Req. In particular, NuVasive notes that all of the embodiments disclosed in the '058 patent involve the monitoring of a nerve through sensing of the condition or response of a muscle. PO Rh'g Req. 4-5. To that end, NuVasive observes the following:

> [T]he '058 patent specification discloses three different ways in which the "sensing a response of a nerve depolarized by said stimulation" of claim 4 may be done, all of which involve sensing a response of the nerve by sensing a response of a muscle coupled to the nerve. These three ways of sensing disclosed in the '058 patent are: (1) observing visual muscle

> twitches in muscle groups associated with the nerve, (2) using a "traditional electromyography (EMG) system," which involves EMG skin electrodes being attached to the patient's skin to monitor electrical activity in the underlying muscle, and (3) using a surgeon-driven EMG system, which similarly involves EMG skin electrodes being attached to the patient's skin to monitor electrical activity in the underlying muscle. See '058 patent, col. 9, line 59 to col. 10, line 18; see also col. 4, lines 13-23; col 10, lines 53-56; col. 11, lines 23-39.

*Id*. (emphasis in original).

NuVasive also directs our attention to particular "determining" and "communicating" associated with each of claims 4 and 10, that, when read in connection with the noted "sensing" steps of those claims, convey that claim 10 would not be understood as being broader than claim 4. *Id*. at 7-8.

*B. Medtronic's Position on Rehearing*

Medtronic contends that the Board did not overlook any matter in connection with the determination in the Decision that claim 10 had been improperly broadened. In that regard, Medtronic urges:

> [T]here is not exact overlap between the sensing of a response of a nerve depolarized by electrical stimulation and sensing an EMG response of a muscle that is coupled to that nerve. While sensing EMG activity in a muscle may suggest potential nerve depolarization, the sensing of the two different activities is not the same. As discussed, depolarization of the nerve may not result in EMG activity of the muscle if there is compression, trauma, or a disease state affecting the nerve or nerve junction. Conversely, an EMG response in a muscle could result from causes unrelated to the direct electrical stimulation of an associated nerve (e.g., irritation of the nerve, mechanical stimulation of the muscle, voluntary movement of the patient etc.).

3PR Comm. 8.

Medtronic characterizes the issue that was, and is, before the Board as "whether 'sensing an electromyographic (EMG) response of a muscle coupled to a nerve depolarized by said stimulation" could possibly cover a scenario not covered by "sensing a response of a nerve depolarized by said stimulation." *Id*. at 11. To that end, Medtronic submits that claim 10 covers the sensing of a muscle's EMG response from something other than a coupled nerve's depolarization, such as "mechanical stimulation of the muscle itself." *Id*. For that reason, Medtronic maintains that claim 10 is broader than claim 4.

*C. Analysis*

We have considered the respective positions of NuVasive and Medtronic. Upon reflection, and with appropriate consideration of the content of claim 10 as a whole in the context of the '058 patent, we conclude that we misapprehended the proper scope of claim 10 in connection with the "sensing" step required by that claim.

In the Decision, we indicated that we were not aware of evidence of record sufficient to convey generally that sensing the response of muscle is a narrower form of sensing a nerve. Decision 10-11. That indication, however, overlooked the particularities of the response that is sensed as a part of claim 10. Claim 10 is directed to a method of accessing a surgical target site. We look carefully at the following steps recited in claim 10:

> sensing an electroymographic (EMG) response of a muscle coupled to a nerve depolarized by said stimulation using an EMG sensor of the nerve monitoring system;

> determining at least one of nerve proximity and nerve direction of said nerve relative to said at least one component of said distraction assembly based upon a stimulation current threshold level required to evoke the sensed EMG response in the muscle coupled to the nerve.

App. Br. Claims App'x.

As set forth above, claim 10 is directed to sensing the response, specifically an EMG response, of a muscle coupled to a nerve via an EMG sensor that is part of a "nerve monitoring system." Thus, claim 10 does not associate the sensing of the muscle response from a general perspective, but from one in which the associated sensing mechanisms are those of a system directed to "nerve monitoring." Furthermore, the next "determining" step of the claim connects "*the* sensed EMG response" (emphasis added) to one that determines characteristics of a nerve, i.e., "nerve proximity" or "nerve direction." Thus, the particular EMG response that is sensed as a part of claim 10 is one that must be able to convey information about the nerve that is coupled to the muscle.

The parties do not disagree that EMG responses in muscles may be produced due to activity of the muscle itself, apart from activity (i.e., depolarization) of the nerve coupled to the muscle. It is the existence of those types of EMG responses, unrelated to nerve activity, that forms the basis for Medtronic's position that claim 10 has been broadened. However, EMG responses arising solely from muscle activity, and not from nerve activity, are not the type of responses that convey the requisite nerve information required by claim 10. As discussed above, the language of claim 10 links the sensed EMG response of the muscle to the depolarization

activity at the nerve, and thus, excludes other muscle responses that are not the result of electrical stimulation of the nerve.[3]

Further still, that reading of the requirements of claim 10 is supported by the Specification of the '058 patent. It is clear that the invention of the '058 patent is not concerned with any direct sensing of a nerve. Rather, as noted by NuVasive, all the described embodiments of the invention concerning "nerve surveillance" or "nerve monitoring" involve sensing the responses of muscles that are coupled to, or associated with, the nerve undergoing surveillance. *See, e.g.,* col. 9, ll. 40-24; col. 11, ll. 5-39. The '058 patent does not express that any and all responses of a muscle are suitable to convey the particular nerve related information that is required as a part of claim 10. Instead, it is the specific EMG responses in a muscle generated due to nerve polarization that operate to impart the desired nerve information. *See, e.g. id.* at col. 10, ll. 46-56; col. 11, ll. 24-34.

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[3] The dissent maintains that it is not apparent that NuVasive has advocated expressly an assessment of the scope of claim 10 as excluding EMG responses arising due to the muscle stimulation not associated with nerve stimulation. However, in our view, NuVasive has expressed such a position in representing to the Board, for instance:

> Thus, Appellant's hypothetical scenarios (involuntary muscle spasm or voluntary muscle movement) ignore half of the claims language in claim 10. To the extent an EMG response is triggered from involuntary muscle spasm or voluntary muscle movement and not from a nerve depolarized by the claimed stimulation step, the EMG response in those scenarios are not within the scope of claim 10 (because the nerve in those scenarios is not "depolarized by said stimulation").

PO Reh'g Req. 8.

For the foregoing reasons, we conclude that when claim 10 is viewed as a whole in light of the Specification, one of ordinary skill in the art would have understood that muscle responses that are independent of, or unrelated to, nerve polarization are not covered by claim 10.

## III. CONCLUSION

After due consideration of NuVasive's Request for Rehearing, we are persuaded that we misapprehended or overlooked in the Decision matters in connection with the proper scope of claim10. Accordingly, we modify the Decision to reflect that the rejection of claims 10-29 based on impermissible broadening under 35 U.S.C. § 314(a) that was proposed by Medtronic is withdrawn.

NuVasive's Request for Rehearing is *granted*.

Pursuant to 37 C.F.R. § 41.79(d), this decision is final for the purpose of judicial review. A party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

GRANTED

DISSENTING OPINION

SONG, *Administrative Patent Judge*.

I respectfully dissent from my colleagues' grant of the Patent Owner, NuVasive's Request for Rehearing, and the modification of the Decision mailed March 18, 2013. In my opinion, our initial analysis in the Decision concluding that claim 10 broadens the scope of claim 4, and thus, violates 35 U.S.C. § 314(a), remains correct for the reasons set forth by Medtronic with which we initially agreed (Decision 8-11).

Claim 4 recites, *inter alia*:

> sensing a response *of a nerve* depolarized by said stimulation.

Claim 10 newly added during the reexamination recites, *inter alia*:

> sensing an electromyographic (EMG) response *of a muscle coupled to a nerve* depolarized by said stimulation using an EMG sensor of the nerve monitoring system.

(Claims App'x., emphasis added).

Thus, while both claims require a nerve depolarized by stimulation, they recite sensing responses of different physiological structures, claim 4 sensing a response of a nerve while new claim 10 senses a response of a muscle. Correspondingly, these claims encompass different subject matter.

NuVasive argues that the Board's Decision overlooked the Specification of the '058 patent that "clearly supports the proper claim interpretation of original claim 4 and [] shows why claim 10 is a subset of claim 4." (PO Rh'g Req. 2). In particular, NuVasive argues that the Board applied an improperly narrow construction of claim 4 which required, "presumably, that the claimed 'sensing' be done ***using direct contact with the nerve***, rather than indirect sensing (via a muscle coupled to the nerve)." (*Id.* at 4, emphasis in original). NuVasive points out that the three different ways for sensing a response of a nerve disclosed in the Specification of the

'058 patent all involve sensing a response of a muscle coupled to the nerve, and that "there is no express disclosure in the '058 patent of sensing a response of a nerve using direct contact with the nerve itself, or using any method of sensing that does not involve the muscle." (*Id.* at 4-7).

Firstly, NuVasive's presumption as to claim 4 is incorrect in that the Decision did not state that claim 4 requires, or is interpreted to require, sensing response of a nerve using direct contact with the nerve. Instead, the Decision states, "[w]ith respect to claim 10, we also agree with Medtronic that sensing the response of a nerve, as in claim 4, is not the same act as sensing the response of a muscle, as in claim 10" and further notes that nerves and muscles are not the same (Decision 10). Thus, the Decision rejects claim 10 as being broader than claim 4, at least in part, based on the arguments submitted by Medtronic as set forth in its Rebuttal Brief filed February 27, 2012 (hereinafter "Req. Reb. Br.") in the subject appeal (Req. Reb. Br. 18).

NuVasive's summarizes its main argument stating:

> Accordingly, properly interpreted in accordance with the required broadest reasonable interpretation, claim 4's recitation of "sensing a response of a nerve" includes within its scope sensing a response of a nerve by sensing a response of a muscle coupled to the nerve (and most certainly includes the narrower preferred embodiment of sensing an EMG response of a muscle coupled to a nerve).

(PO Rh'g Req. 9).

I do not dispute that under the broadest reasonable interpretation in view of the Specification of the '058 patent, that claim 4 includes sensing a response of a nerve by monitoring an electromyographic (EMG) response of

a muscle coupled to a nerve. However, NuVasive's arguments are pertinent to issues of the scope of claim 4 and whether there is written descriptive support for claim 10. These issues are not the determinative as to whether claim 10 is broader than claim 4 under 35 U.S.C. § 314(a) which, in this case, requires determining whether the new claim 10 encompasses any subject matter that was not encompassed by claim 4. In this regard, a claim "is broader in scope than the original claims if it contains within its scope any conceivable apparatus or process which would not have infringed the original patent," and "[a] claim that is broader in any respect is considered to be broader than the original claims even though it may be narrower in other respects." *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1374 (Fed. Cir. 2006); *see also In re Freeman*, 30 F.3d 1459, 1464 (Fed. Cir. 1994).

The record indicates that there are various reasons why the scope of claim 10 is not merely just a subset of "sensing a response of a nerve" recited in claim 4, but rather, encompasses subject matter beyond claim 4. Medtronic has set forth such reasons in its Rebuttal Brief and has further explained and supplemented its arguments in its opposition to NuVasive's Request for Rehearing (*see generally*, Req. Reb. Br. 18; 3PR Comm. 4-9). These reasons include the fact that EMG response of a muscle may be derived from involuntary muscle spasm or voluntary muscle movement, and depolarization of the nerve does not necessarily result in a measurable EMG response in the muscle for reasons such as nerve damage (*id.*). As the majority acknowledges, the parties do not disagree that EMG responses in muscles may be produced apart from activity of the nerve coupled thereto.

Thus, the record indicates that EMG response of a muscle is *not always* directly correlated to a nerve coupled to the muscle, but can be independent of/from the coupled nerve regardless of whether or not the coupled nerve is depolarized by the stimulation. It also follows that EMG response of a muscle may be due to both the coupled depolarized nerve, and other non-nerve related causes noted. Hence, whereas claim 4 would not encompass such non-nerve related causes for EMG responses of the muscle, the language of new claim 10 would encompass such responses so as to be broader than claim 4 in this respect.

NuVasive's misunderstanding of the pertinent issue is exemplified in its argument that:

> all of [Medtronic's] grounds for rejection for claim 4, including those adopted by the Board, rely on prior art that allegedly shows the 'sensing a response of a nerve' by indirect means, namely sensing the nerve response by sensing the response of an associated muscle.

(PO Rh'g Req. 8).

NuVasive further observes that the Board entered various rejections based on prior art that sense nerve response by sensing the response of an associated muscle, and asserts that Medtronic contradicts itself in making the broadening argument as to claim 10 while also relying on references that sense the response of a muscle to sense nerve response (*id.* at 9-10). However, there is no contradiction because the scope of the language of claim 10, while overlapping with the scope of the language of claim 4, encompasses subject matter beyond that of claim 4.

As noted, NuVasive does not disagree or factually challenge the reasons in the record as to why EMG response of a muscle may not be

correlated to a nerve coupled thereto (*see generally*, PO Req. Rh'g 7-9).

Instead, NuVasive argues that:

> To the extent an EMG response is triggered from involuntary muscle spasm or voluntary muscle movement and not from a nerve depolarized by the claimed stimulation step, the EMG response in those scenarios are not within the scope of claim 10 (because the nerve in those scenarios is not "depolarized by said stimulation").

(PO Rh'g Req. 8).

However, this argument relies on limitations not appearing in claim 10. The pertinent limitation recites that a muscle is coupled to the nerve and it is the nerve that is "depolarized by said stimulation." The only requirement in this limitation as to the relationship between the sensed EMG response and the nerve is that the EMG response be "*of a muscle*" which must be coupled to the depolarized nerve. The pertinent limitation of claim 10 does not require the sensed EMG response of the muscle to be caused by the depolarized nerve coupled thereto.

The majority notes that the Specification of the '058 patent is directed to sensing EMG response of a muscle to derive nerve information, and refers to the language of the claim reciting a "nerve monitoring system" and the subsequent "determining" step as connecting the sensed EMG response of the muscle to "one that must be able to convey information about the nerve that is coupled to the muscle" such as proximity and direction. Based thereon, the majority concludes that "EMG responses arising solely from muscle activity, and not from nerve activity, are not the type of responses that convey the requisite nerve information required by claim 10," and thus,

muscle responses "that are not the result of electrical stimulation of the nerve" are excluded from the language of claim 10.

Initially, it not apparent where NuVasive has expressly advocated the interpretation of claim 10 adopted by the majority so that prosecution estoppel would apply in interpreting claim 10.[4] Regardless, it appears that the majority is reading exclusion limitations into claim 10. I do not view the lack of disclosure with respect to EMG responses of a muscle that are not attributable to the coupled nerve in the Specification of the '058 patent as an exclusion of such EMG responses that limits the scope of claim 10.[5] As to the majority's reference to the Specification of the '058 patent, I view such analysis to be similar to that of NuVasive, that is, that claim 10 is adequately supported by the Specification. However, as noted, this speaks little to whether claim 10 encompasses subject matter that claim 4 did not.

As to the limitation of claim 10 that recites the step of determining the nerve proximity or direction "based upon *a stimulation current threshold level* required to evoke the sensed EMG response in the muscle coupled to the nerve," it is important to observe that the recited "a stimulation current threshold level" is merely correlated to the sensed EMG response *of the muscle* rather than to an EMG response caused by the nerve that has been

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[4] In this regard, whereas the broadening rejection under 35 U.S.C. § 314(a) was entered as a New Ground thereby affording NuVasive an opportunity to reopen prosecution to submit clarifying amendments to claim 10, NuVasive has chosen to forego that opportunity.

[5] In a situation where the EMG response of the muscle may only be partially attributable to the depolarized nerve, it is clear that the majority would view such non-nerve based portion of the EMG response of muscles as being excluded from claim 10.

depolarized. Hence, I do not view this limitation of claim 10 as necessitating the narrow construction adopted by the majority. To the contrary, claim 10 allows the recited stimulation current threshold level to be based on the sensed non-nerve associated EMG response of the muscle which would not have been encompassed by claim 4. It is not apparent how claim 10 precludes this non-nerve based *threshold level* from being used as a basis to determine nerve proximity or direction, for example, by stimulating the nerve to this non-nerve based threshold level. Again, a claim "is broader in scope than the original claims if it contains within its scope any conceivable apparatus or process which would not have infringed the original patent." *Medtronic*, 465 F.3d at 1374.

For the above reasons, I respectfully dissent.

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC.
Requester

v.

NUVASIVE, INC.
Patent Owner

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Appeal 2012-009491
Reexamination Control 95/001,247
Patent 7,582,058
Technology Center 3900

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Before JEFFREY B. ROBERTSON, DANIEL S. SONG, and JOSIAH C. COCKS, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

DECISION ON REQUESTER'S
REQUEST FOR REHEARING

## I. INTRODUCTION

Third Party Requester, Medtronic, Inc. ("Medtronic"), requests rehearing of the Decision mailed March 18, 2013 ("Decision").[1] Patent Owner NuVasive, Inc. ("NuVasive") has filed comments in response to Medtronic's Request.[2]

In the Decision, we affirmed the Examiner's determination not to adopt proposed grounds of rejections for claims 10-29 based on the following combination of references: (a) Koros, Michelson, Foley '871, Kelleher, and NIM Guide (hereinafter "Ground (a)", Rejection (17) in the Decision); and (b) Smith, Michelson, Koros, Marino, and NIM Guide ("Ground (b)", Rejection (18) in the Decision). Decision 46. In its Request for Rehearing, Medtronic requests that the Board reconsider our affirmance of the Examiner's determination with respect to those two proposed grounds. 3PR Rh'g. Req. 2.

We have considered Medtronic's request but decline to modify the Decision. Accordingly, Medtronic's Request for Rehearing is *denied*.

## II. DISCUSSION

A "request for rehearing must state with particularity the points believed to have been misapprehended or overlooked in rendering the Board's opinion reflecting its decision." 37 C.F.R. § 41.79(b)(1). Here,

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[1] *See* Medtronic's "Request for Rehearing" filed May 20, 2013 ("3PR Rh'g Req.").

[2] *See* NuVasive's "Comments in Opposition to Rehearing Request Under 37 C.F.R. § 41.79(c)" filed June 20, 2013.

Medtronic contends the following: "Requestor submits that the PTAB misapprehended the meaning of 'distractor blades' as used in Koros[3], which affected the application of Koros against the 'retractor blade' recited in the pending claims." 3PR Rh'g Req. 2.

In the Decision, we were unpersuaded by Medtronic's assessment that the prior art accounts for the feature in claim 10 of a "locking member" that is "releasably received within a passageway of the first retractor blade" of a retractor assembly. Decision 39-40. In particular, in advocating for the grounds of rejection involving Koros, Medtronic directed our attention to "retractor blades 30" of Koros and to "screws 83 that are releasably received in passageways 82 and 86 in the retractor blades…"[4] In light of those teachings of Koros, Medtronic argued that claim 10 would have been obvious in view of the prior art. However, as we observed in the Decision, Koros discloses two sets of "blades," those characterized as "distractor blades 32," and those characterized as "retractor blades 30." Decision 40. Koros associates its screws 83 with distractor blades 32 rather than retractor blades 30. Because we were not persuaded that Koros contemplated the use of its screws 83 with retractor blades 30, we did not discern error in the Examiner's determination not to adopt the proposed rejections. *Id*.

In its Request for Rehearing, Medtronic argues that the Board overlooked that Koros's "distractor" blades 32 may also be considered as "retractor" blades. 3PR Rh'g Req. 3-4. In that regard, Medtronic now contends that distractor blades 32 and associated screws 83 meet the

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[3] U.S. Patent No. 6,139,493 issued October 31, 2000.

[4] *See* page 39 of Medtronic's Appeal Brief filed September 6, 2011.

retractor blade and locking mechanism requirements of claim 10. *Id*. As support for that position, Medtronic directs our attention to "Claim Chart K," "Claim Chart L," and pages 15-16 of the Rebuttal Brief filed February 27, 2012 ("Reb. Br."). We understand the two referenced claim charts to be those that were filed March 19, 2010 as a part of Medtronic's "Response to Patent Owner's Amendment," with Claim Chart K directed to Ground (a) and Claim Chart L directed to Ground (b).

*Ground (a)*

In reviewing the above-noted Claim Chart K concerning Ground (a), we observe that, with respect to claim10, the chart makes no mention of Koros's "distractor blades 32," or equates those particular distractor blades with the retractor blades of claim 10. Rather, as described in Claim Chart K, the blades relied upon are "retractor blades 30," and associated structures and operation thereof. Claim Chart K, p. 4. Claim 10 requires a "pair of directly opposing retractor blades being releasably lockable to an external assembly having handle arms." In explaining how that requirement is met, Medtronic urged that: "The retractor blades 30 of Koros are releasably lockable to a frame 10 (eternal assembly) having arms 18 and 22," citing to Figure 1 and column 7, ll. 6-12. Claim Chart K, p. 4. Review of the cited portions of Koros reveals that frame 10 and arms 18 and 22 are structures interconnected to, and operable with, retractor blades 30 and not distractor blades 32.

Elsewhere in Claim Chart K, in accounting for features of claims that ultimately depend from claim 10 (e.g., claim 15), Medtronic points to components such as "flanges 34," and "bosses 36" in Koros in accounting

for required claim features directed to a "first locking bolt" associated with the first retractor blade. Claim Chart K, p. 7. Koros's flanges 34 and bosses 36 are components that are structurally and functionally associated with retractor blades 30 and not distractor blades 32. Koros, col. 6, ll. 11-13; Fig. 2.

In the Rebuttal Brief, Medronic stated the following:

> Koros discloses various retractor blades including "blade 32." Koros, col. 6, l. 45. Appellant is unclear what position Respondent is attempting to argue by asserting that Koros does not disclose inserting screw 83 through blade 30 when Koros clearly describes inserting screw 83 through a passageway in blade 32. That one retractor blade is assigned reference numeral 30 and another is assigned reference number 32 is irrelevant to whether the document, as a whole, shows a locking member (screw 83) being inserted through a passage (passage 82) in a retractor blade (blade 32).

Reb. Br., pp. 15-16.

To the extent that Medtronic generally urged in its Rebuttal Brief that Koros's "blade 32" may be considered as the retractor blade required by claim 10, Medtronic did not explain adequately how Koros's blade 32 as a "retractor blade" also accounts for other features of the retractor blades required by claim 10, and those claims that depend therefrom. For instance, Medtronic did not articulate how the feature of the blades in being "releasably lockable to an external assembly having handle arms" is met in connection with blades 32. As discussed above, Medtronic's proposed Ground (a) accounts for that quoted limitation by reference to components of Koros's retraction device associated with retractor blade 30, i.e. frame 10 and arms 18 and 22, and not distractor blades 32. Similarly, Medtronic also

did not explain how other features required by the involved claims, including the "first locking bolt" of claim 15 are met by features associated with distractor blades 32.

Furthermore, in connection with its ground (a), Medtronic did not present any credible basis for concluding that it would have been obvious to implement Koros's locking mechanism 83 and tubular guide 82 onto Koros's retractor blades 30. To the extent that Medtronic now makes such a contention, it is untimely. In this situation, a request for rehearing is not an opportunity for a party to make new arguments. *See* 37 C.F.R. § 41.79(b).

*Ground (b)*

In reviewing Medtronic's Claim Chart L directed to Ground (b), we observe that, in connection with claim 10, the claim chart makes no mention of Koros's "distractor blades 32" as constituting a component that corresponds to the required retractor blades. Instead, as set forth in Claim Chart L, Medtronic equated components of a different prior art reference, Smith[5]. In that regard, Medtronic likened Smith's elements 22 and 42 to the retractor blades required by claim 10. Claim Chart L, p. 4. Those elements are characterized, respectively, as a "first portion" and a "second portion" of retractor 20 and each are formed as a "semi-cylindrical body." Smith, col. 2, l. 55 - col. 3, l. 25. The first and second portions pivot with respect to one another so as to transition from an unexpanded configuration to a configuration in which the retractor is expanded through skin and tissue to increase the size of working channel 50. *Id*.

[5] U.S. Patent 7,261,688 B2 issued August 28, 2007.

Although each of Smith and Koros is described as being "retractor" systems, it is evident that the configuration of Smith's retractor system in forming a working channel through a pivoting relationship between two semi-cylindrical bodies is distinct from the operation of Koros's system. In Koros, there are two separate sets of opposing blades, namely retractor blades 30 on the one hand and distractor blades 32 on the other. Retractor blades 30 are associated with retractor 10 and distractor blades 32 are associated with distractor 12. Koros, col. 5, ll. 57-58. The blades of the retractor and distractor are moved relative one another by virtue of "moveable arms" and "crank mechanisms." *Id*. at col. 5, ll. 60-63. Distractor 12 is also characterized as an "[o]ffset distractor fame." *Id*. at col. 7, ll. 13. Distractor blades 32 of the offset distractor frame are outfitted with tubular guides 82 and 86 that receive fixation screws 83. *Id*. at col. 6, ll. 58-64. As set forth in Koros:

> Offset distractor frame 12 is then positioned in the incision with fixation screws 83 screwed into vertebrae 94 and 96 of spine 92 on opposite sides of affected disc 98. Fixation screws 83 firmly hold offset retractor fame in position allowing adjacent vertebrae 94 and 96 to be spread providing a clear view of the operating site.

Koros, col. 7, ll. 13-18.

With respect to the offset distractor fame, Koros also explains that "[t]he adjacent vertebrae can then be gently spread by cranking the right angle offset distractor frame." *Id*. at col. 4, ll. 53-55.

Thus, in Koros, the fixation screws 83 are anchored into adjacent vertebrae and operate in conjunction with moveable arms and crank mechanisms, which form part of an offset distractor frame in a distractor

system, to spread adjacent vertebrae. Koros does not indicate that the fixation screws 83, taken alone, provide any particular functions disconnected from the other components of Koros's distractor system that facilitate bone spreading. Medtronic generally relies on Koros's fixation screws as providing "stability and support" for other retractor blades, such as those of Smith. *See* Claim Chart L, 5. However, it is not Koros's disclosure that the fixation screws themselves would provide those functions in any and all retractor blade systems. Medtronic does not explain persuasively why a person of ordinary skill in the art would have sought to implement Koros's fixation screws in other retractor assemblies that are unconcerned with, and not configured to, provide bone spreading functionality, such as the tissue retraction system of Smith. Yet, that is the premise underpinning Medtronic's assertions of obviousness with respect to NuVasive's claim 10 in view of the combined teachings of Smith, Michelson, Koros, Marino, and NIM Guide.

We have considered Medtronic's Request for Rehearing in conjunction with our decision to affirm the Examiner's non-adoption of a proposed rejection of claim 10 based on the above-noted prior art. However, we are not persuaded that the combined teachings of those references, in the manner urged by Medtronic, adequately account for the feature the claim 10 of "a locking member releasably received within the first passageway of the first retractor blade." *See* App. Br. Claim App'x, iv. That was a determination we made in the Decision. Decision 40. Medtronic has not shown that we misapprehend or overlooked anything in that regard.

## III. CONCLUSION

After due consideration of Medtronic's Request for Rehearing, we are not persuaded that the Board misapprehended or overlooked any points in the Decision. Accordingly, while we have considered the Request, we decline to modify the Decision.

The Request for Rehearing is *denied*.

Pursuant to 37 C.F.R. § 41.79(d), this decision is final for the purpose of judicial review. A party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

DENIED

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US007582058B1

# (12) United States Patent
Miles et al.

(10) Patent No.: US 7,582,058 B1
(45) Date of Patent: Sep. 1, 2009

(54) **SURGICAL ACCESS SYSTEM AND RELATED METHODS**

(75) Inventors: **Patrick Miles**, San Diego, CA (US); **Scot Martinelli**, San Diego, CA (US); **Eric Finley**, San Diego, CA (US); **James Gharib**, San Diego, CA (US); **Allen Farquhar**, San Diego, CA (US); **Norbert Kaula**, Arvada, CO (US); **Jeffrey Blewett**, San Diego, CA (US); **Goretti Medeiros**, legal representative, Plantsville, CT (US)

(73) Assignee: **NuVasive, Inc.**, San Diego, CA (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 191 days.

(21) Appl. No.: **10/608,362**

(22) Filed: **Jun. 26, 2003**

**Related U.S. Application Data**

(60) Provisional application No. 60/392,214, filed on Jun. 26, 2002.

(51) **Int. Cl.**
*A61B 1/32* (2006.01)
*A61B 5/04* (2006.01)

(52) **U.S. Cl.** ..... **600/202**; 600/214; 600/546; 600/554; 607/2

(58) **Field of Classification Search** ..... 600/201–207, 600/490, 493–496, 210, 214, 215, 233, 219, 600/554, 546, 221; 606/99; 607/2
See application file for complete search history.

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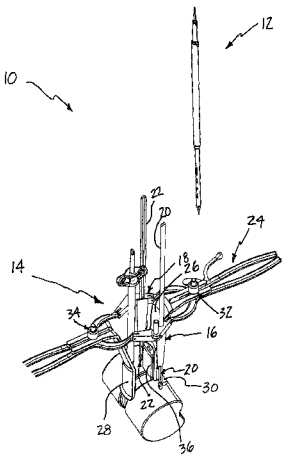
(57) **ABSTRACT**

A system for accessing a surgical target site and related methods, involving an initial distraction system for creating an initial distraction corridor, and an assembly capable of distracting from the initial distraction corridor to a secondary distraction corridor and thereafter sequentially receiving a plurality of retractor blades for retracting from the secondary distraction corridor to thereby create an operative corridor to the surgical target site, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target site.

**9 Claims, 33 Drawing Sheets**



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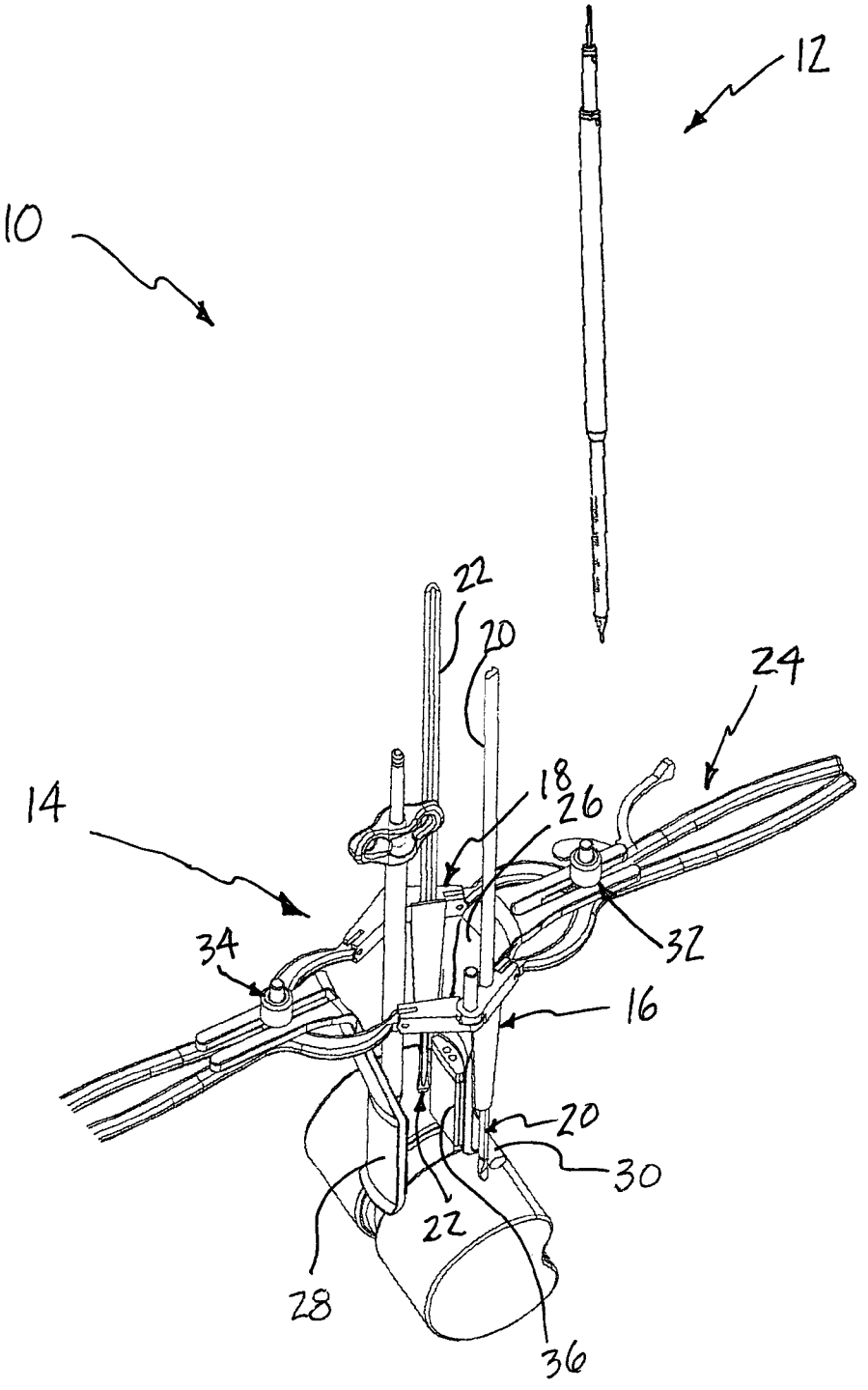



FIG. 1

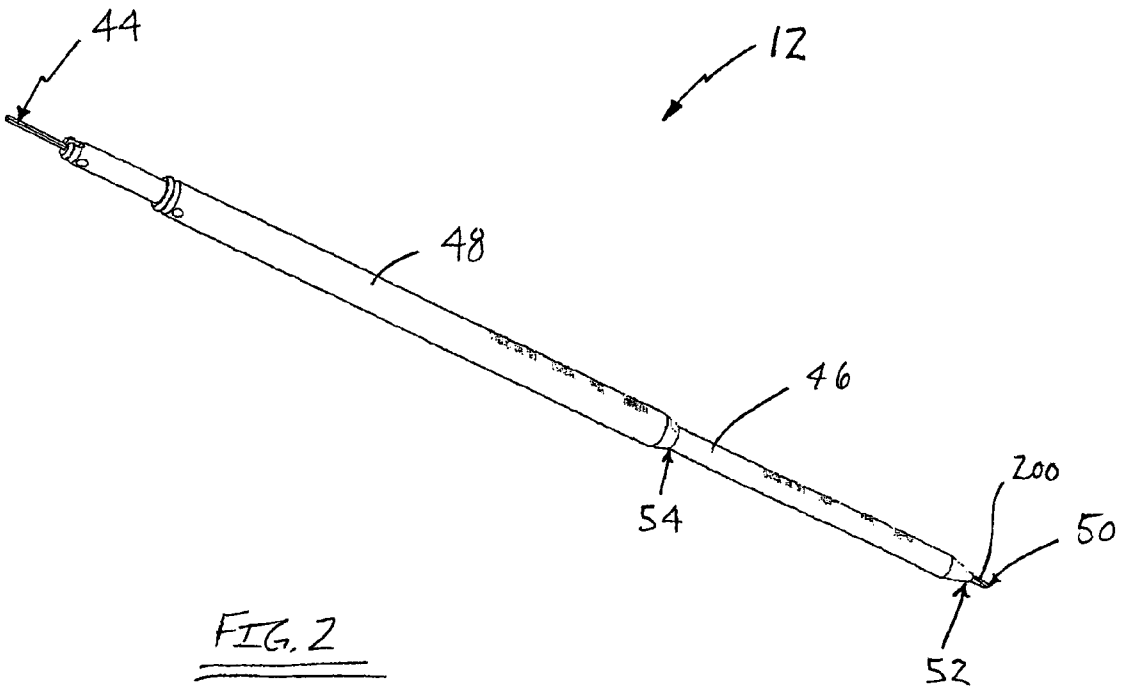



FIG. 2

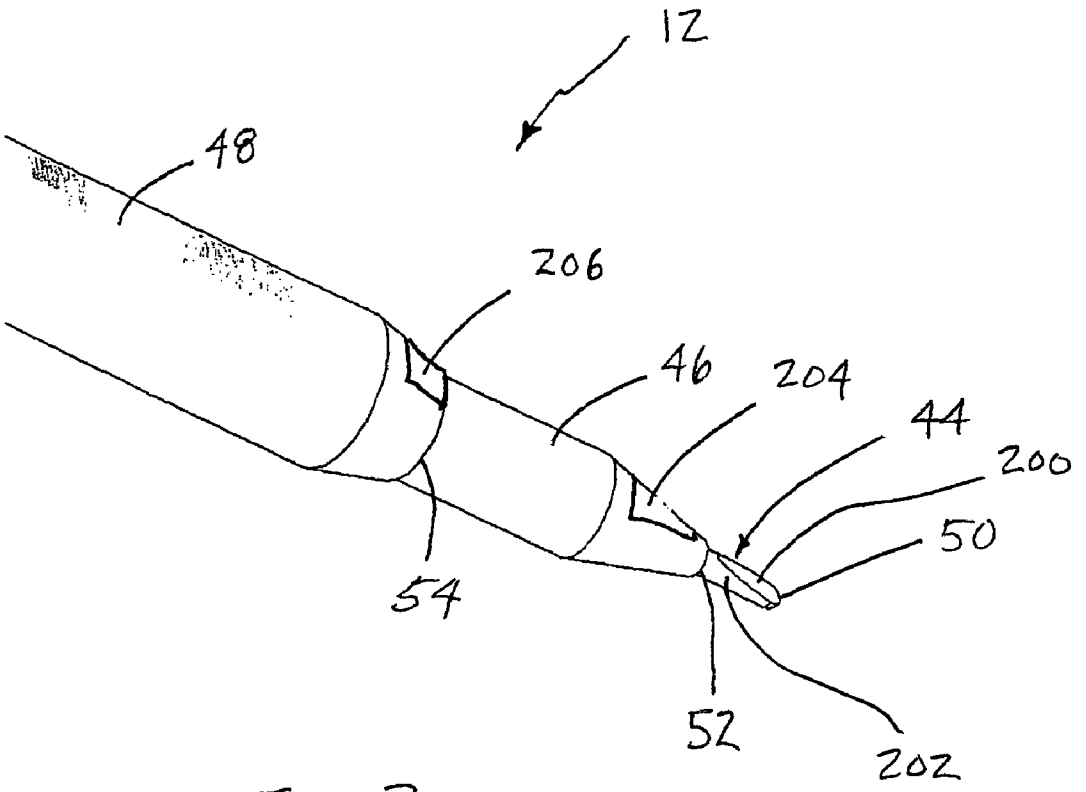



FIG. 3

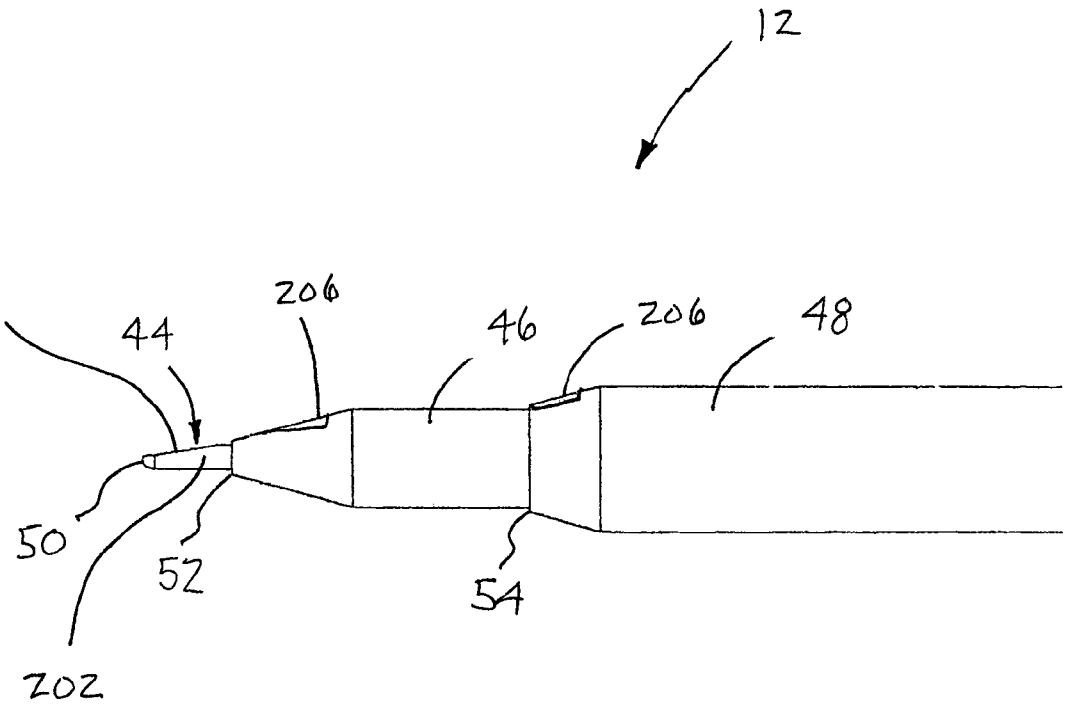



FIG. 4

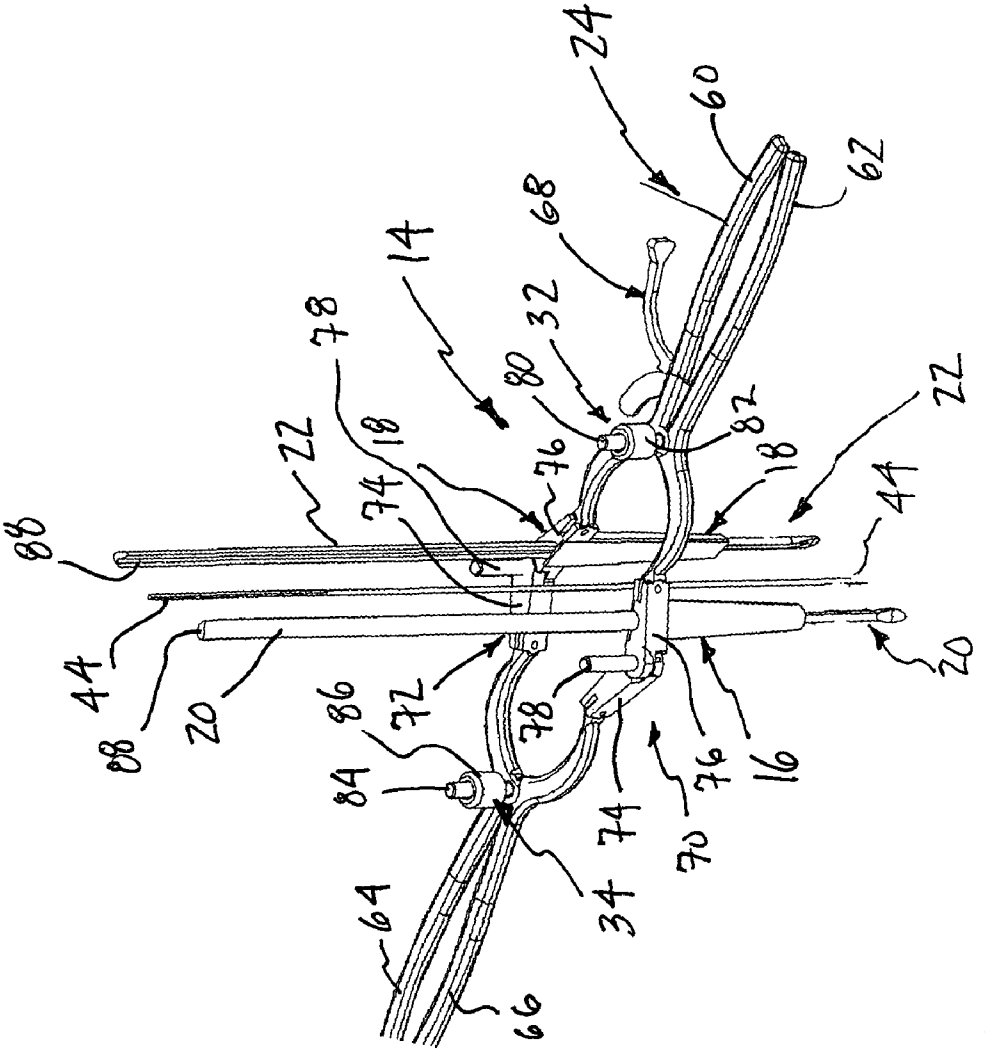
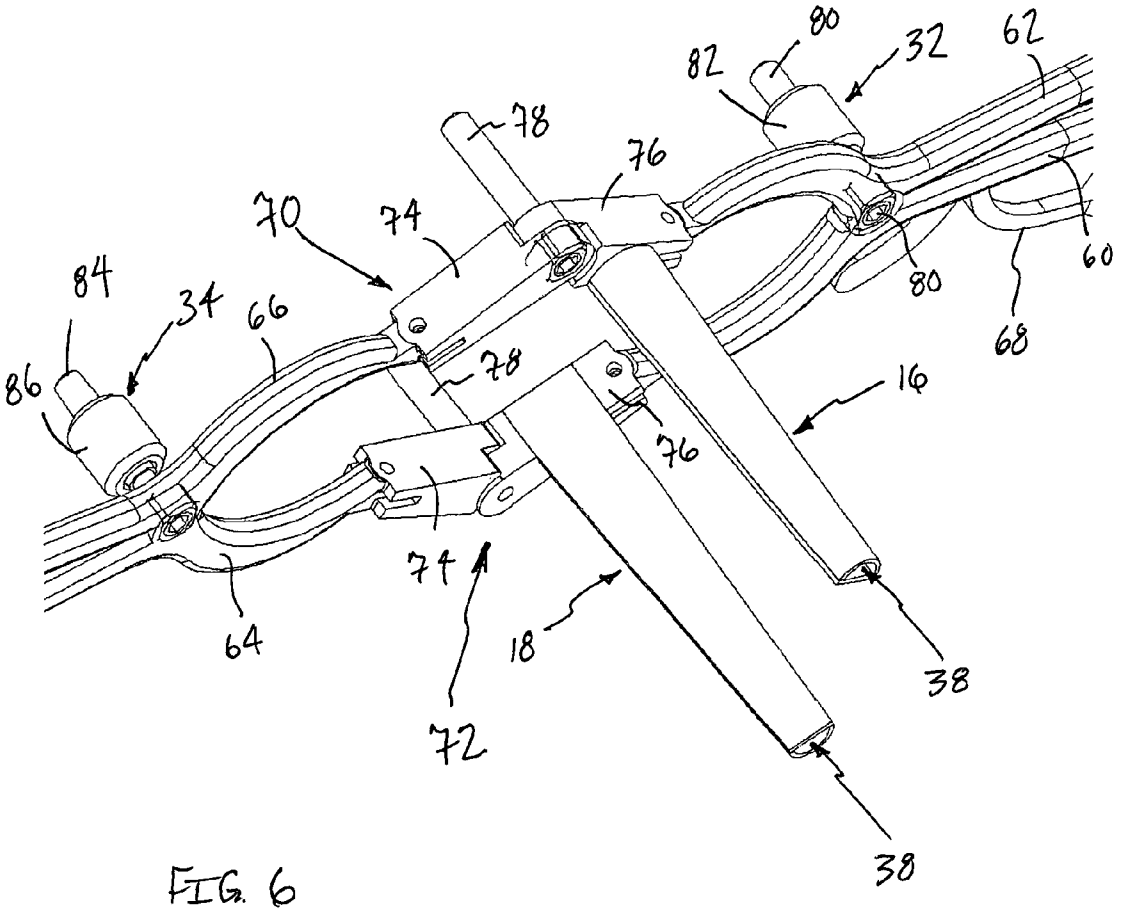



FIG. 5

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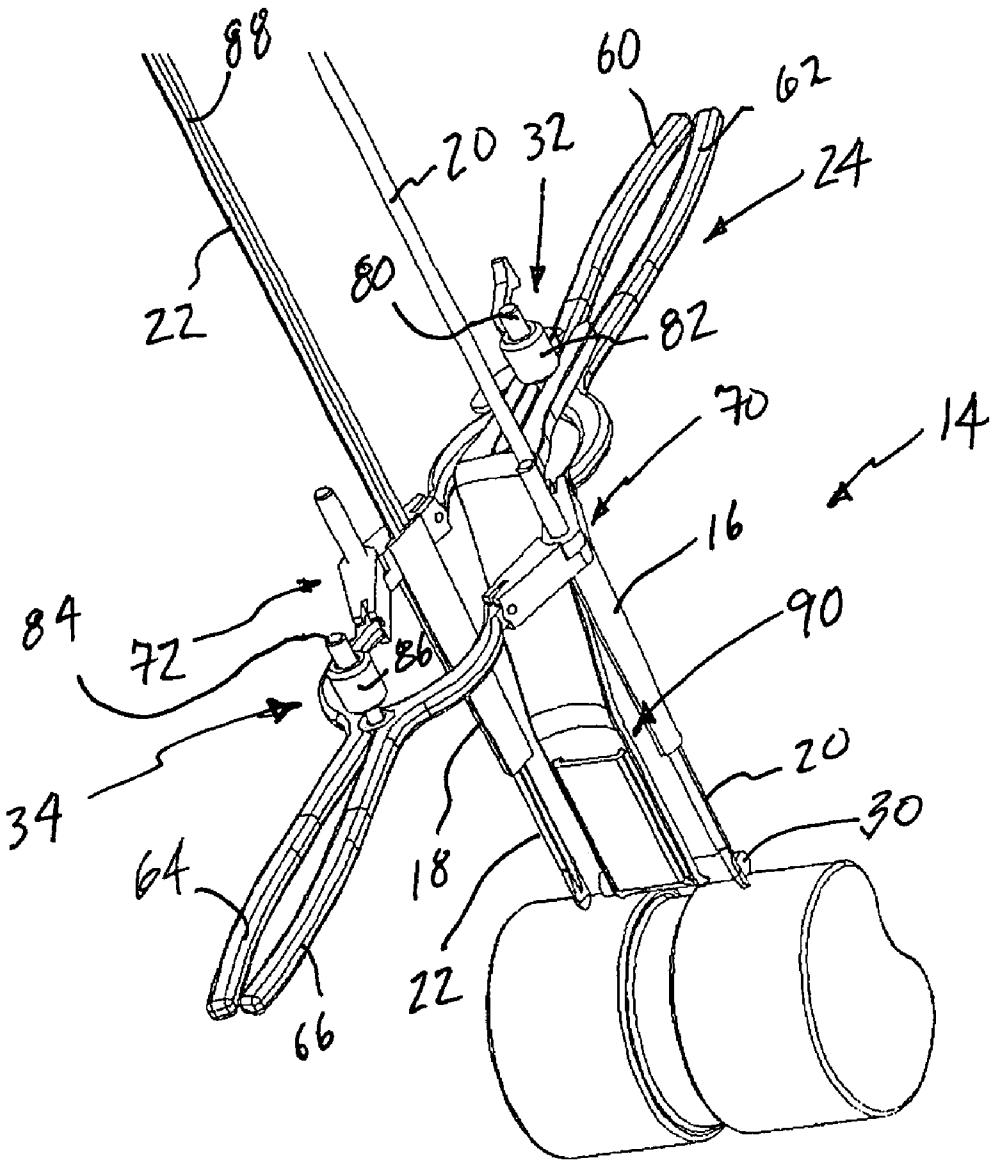



FIG. 7

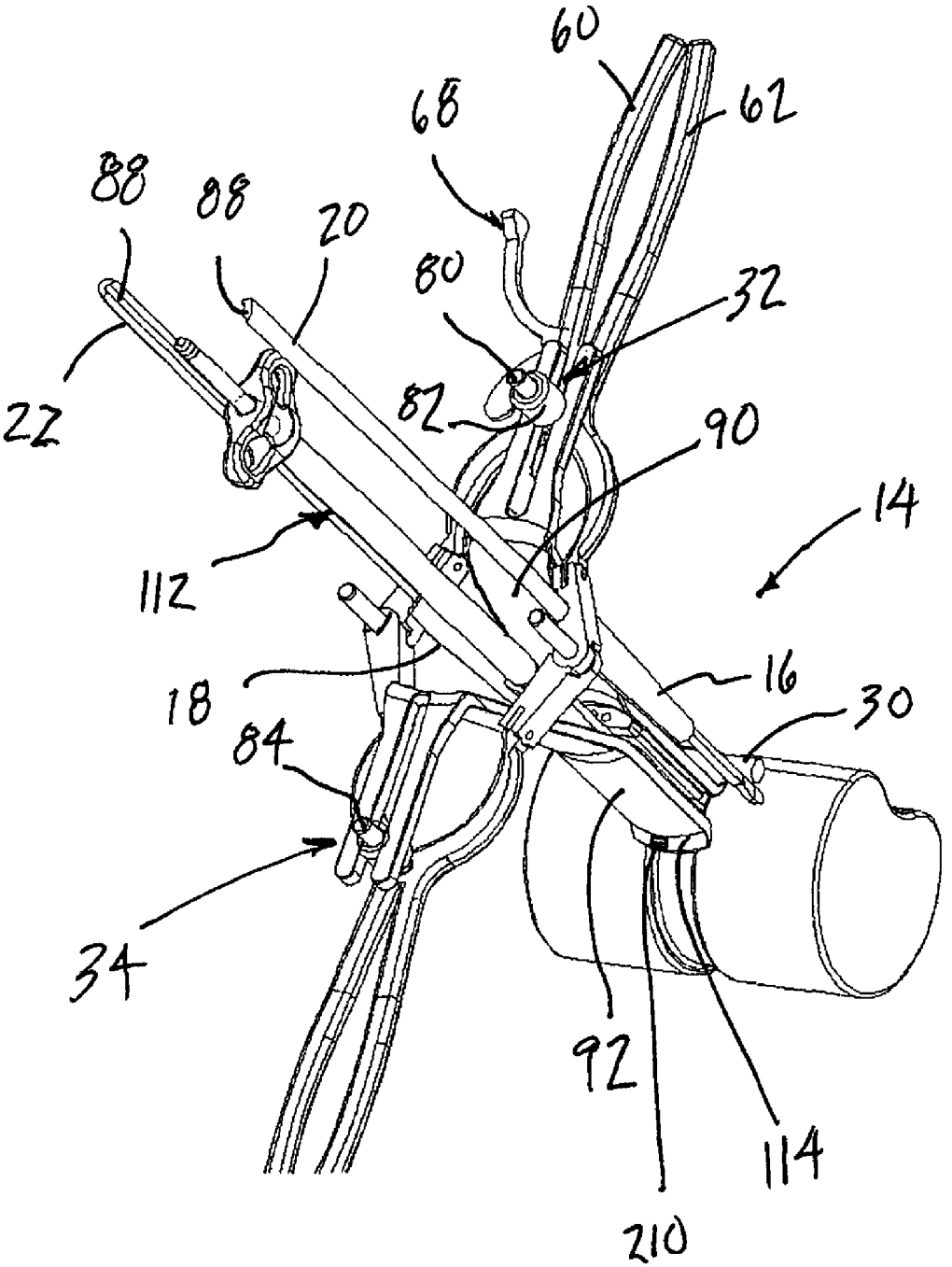



FIG. 8

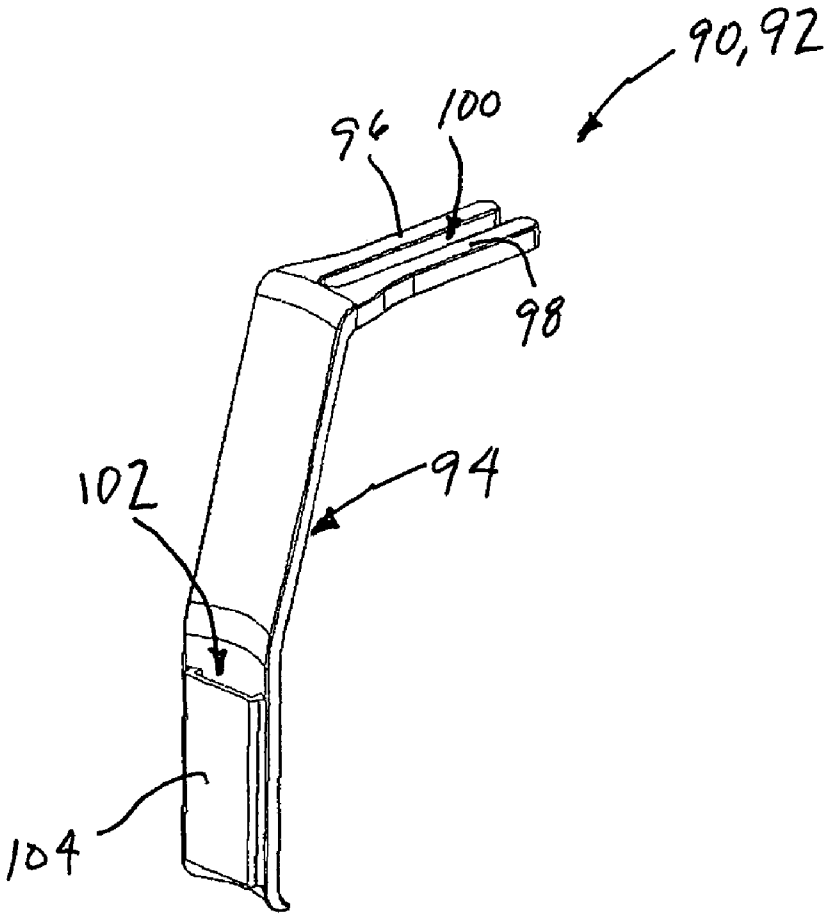



FIG. 9

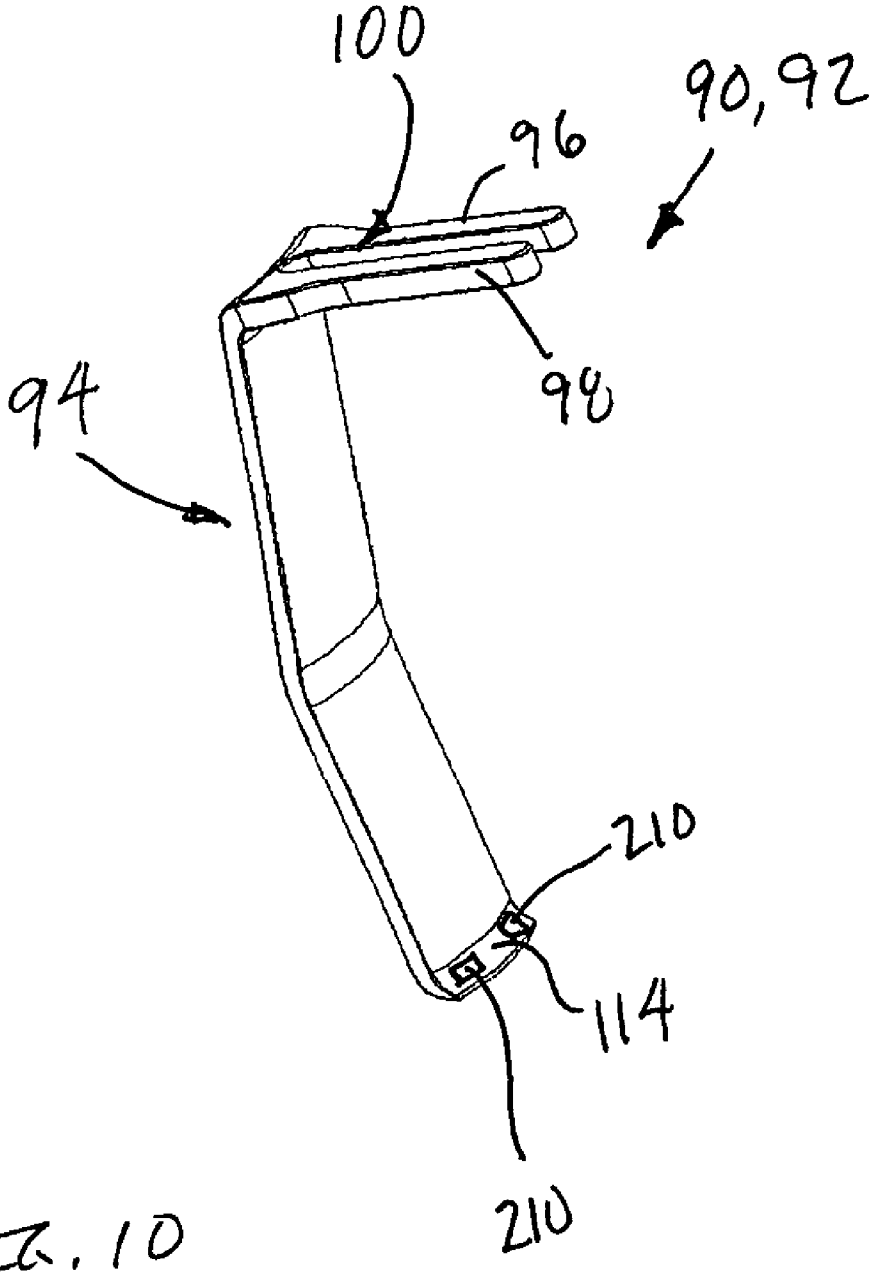



FIG. 10

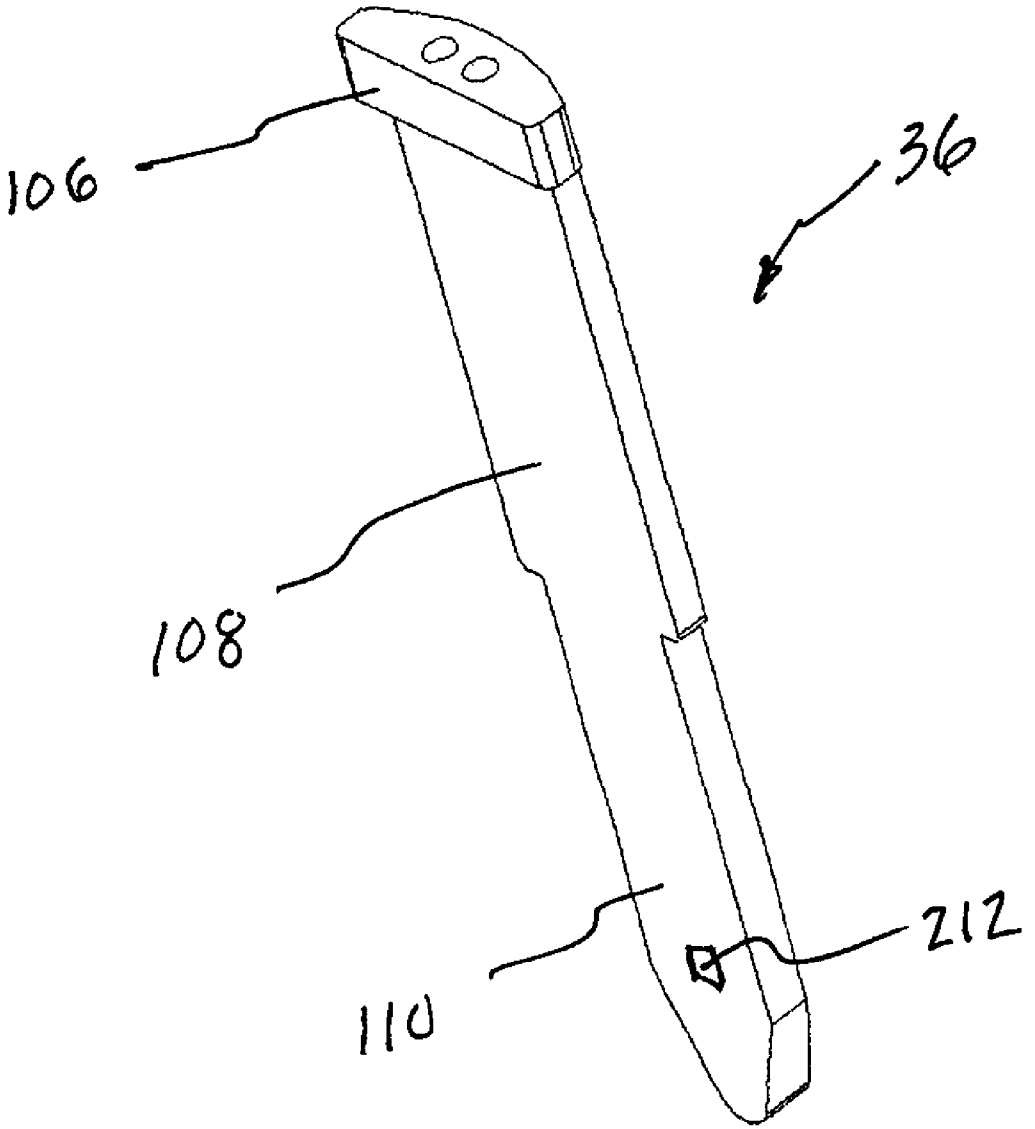



FIG. 11

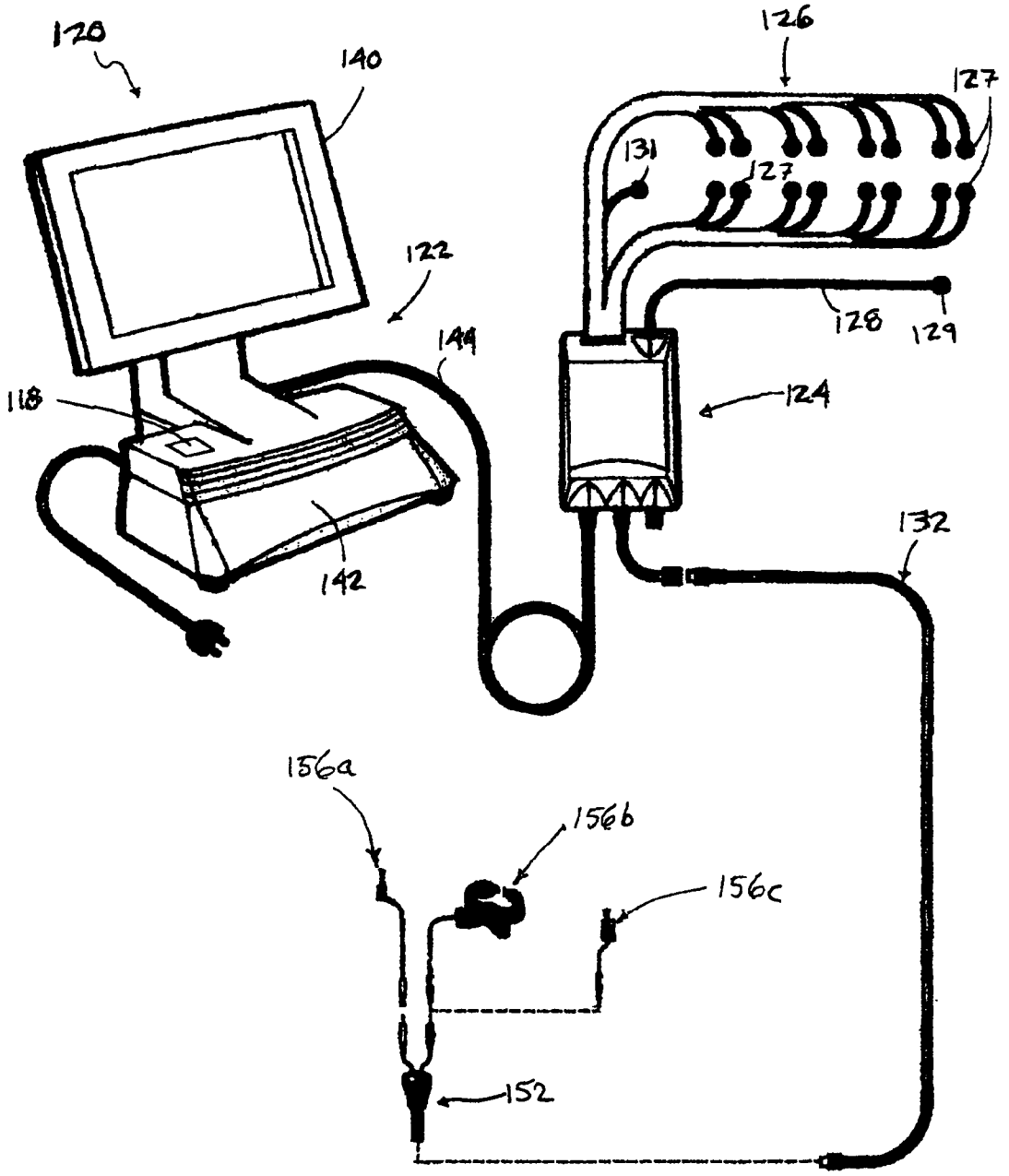

120
140
126
127
131
127
122
128
129
149
118
124
132
142
156a
156b
156c
152

FIG. 12

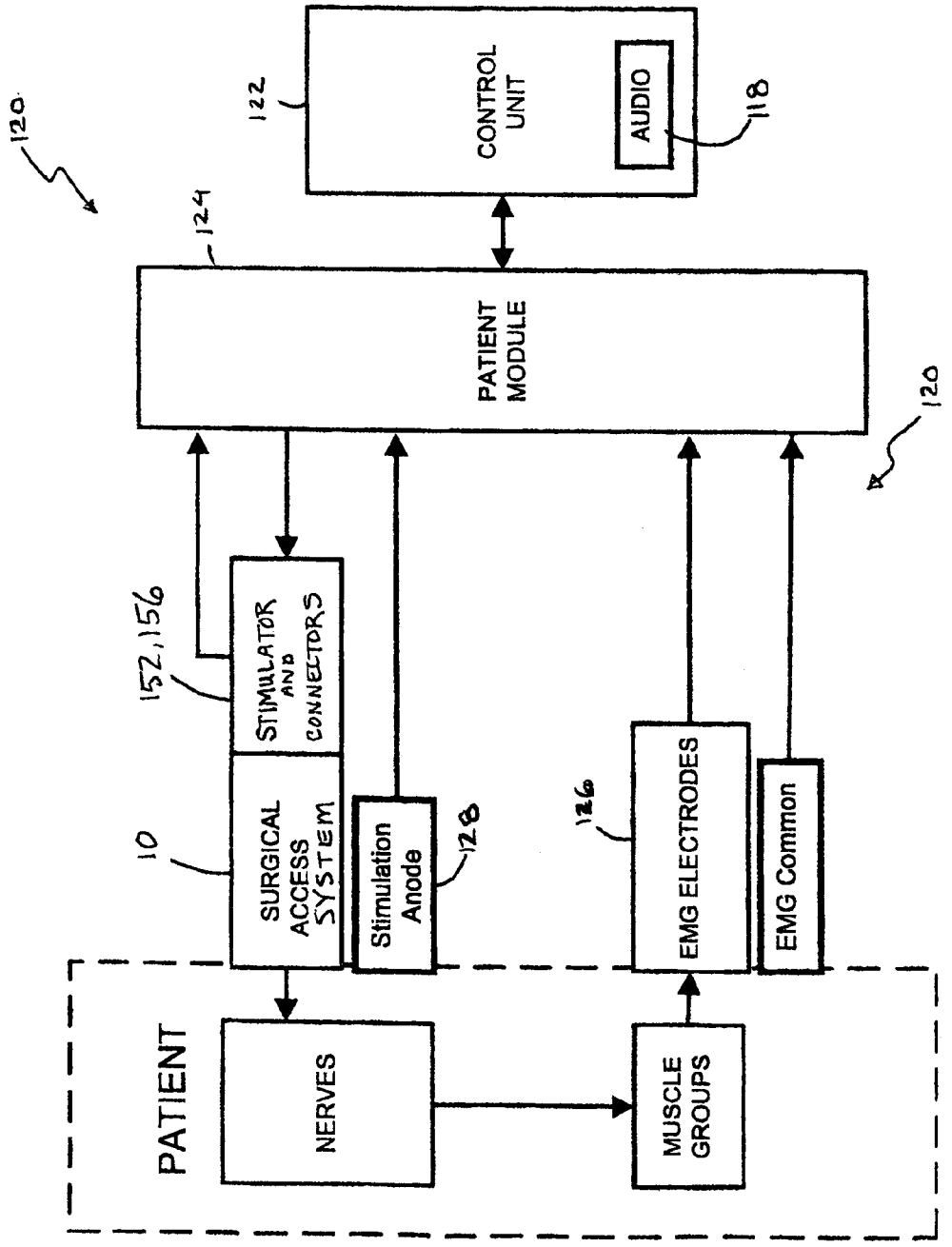

120
122
CONTROL UNIT
AUDIO
118
124
PATIENT MODULE
120
152, 156
STIMULATOR AND CONNECTORS
10
SURGICAL ACCESS SYSTEM
Stimulation Anode
128
126
EMG ELECTRODES
EMG Common
PATIENT
NERVES
MUSCLE GROUPS

FIG. 13

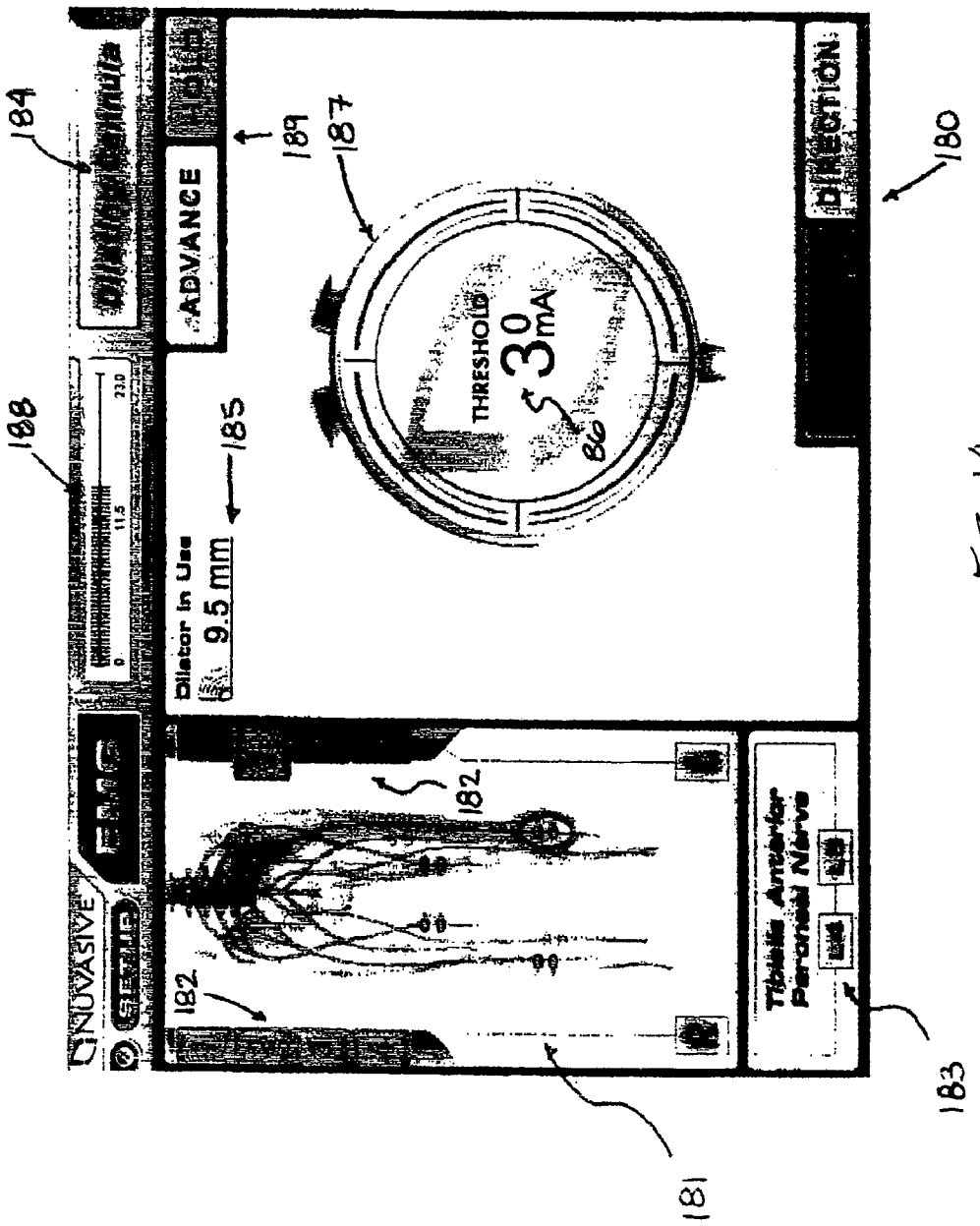

NUVASIVE
EMG
GET ID
ADVANCE
Dilator In Use
9.5 mm
THRESHOLD
30 mA
86
DIRECTION
Tibialis Anterior
Peroneal Nerve
184
188
185
189
187
180
182
182
181
183

FIG. 14

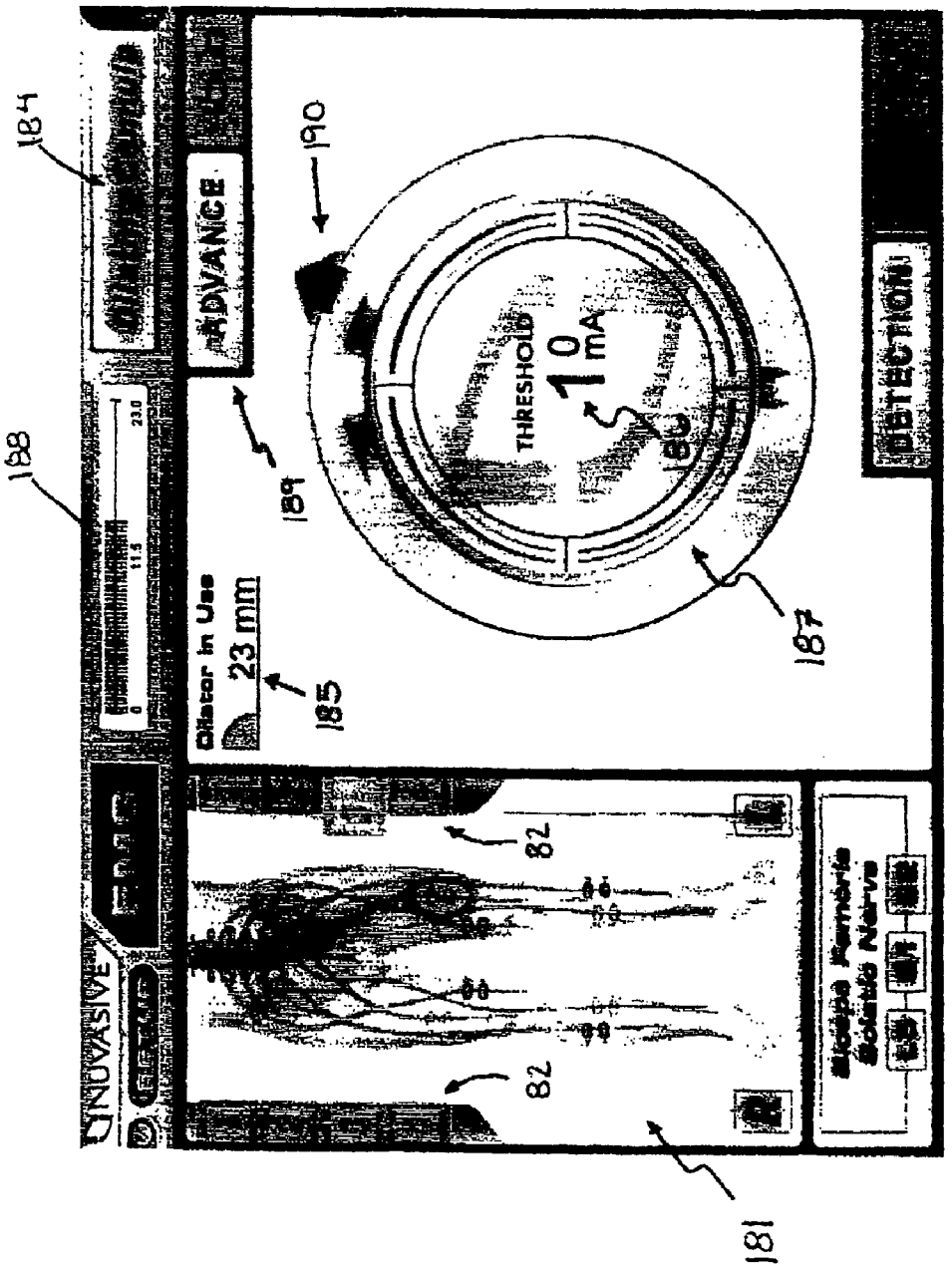

NUVASIVE
ADVANCE
Dilator in Use
23 mm
THRESHOLD
10 mA
DETECTION
Medial Peroneal
Sciatic Nerve
82
82
181
183
184
185
187
188
189
190
180

FIG. 15

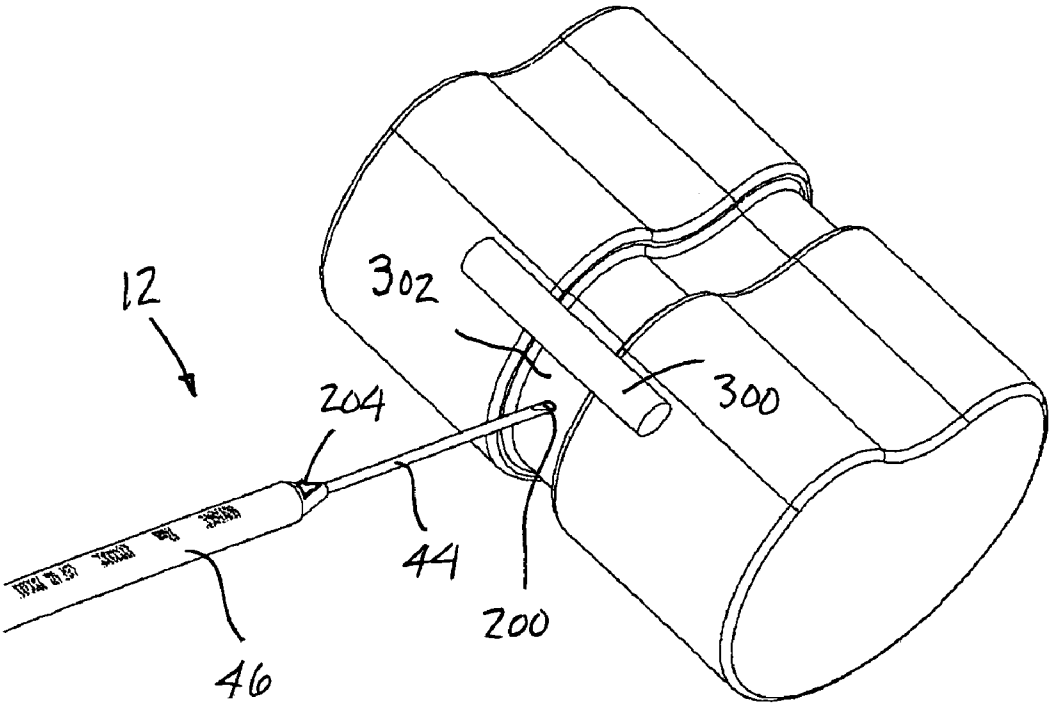



FIG. 16

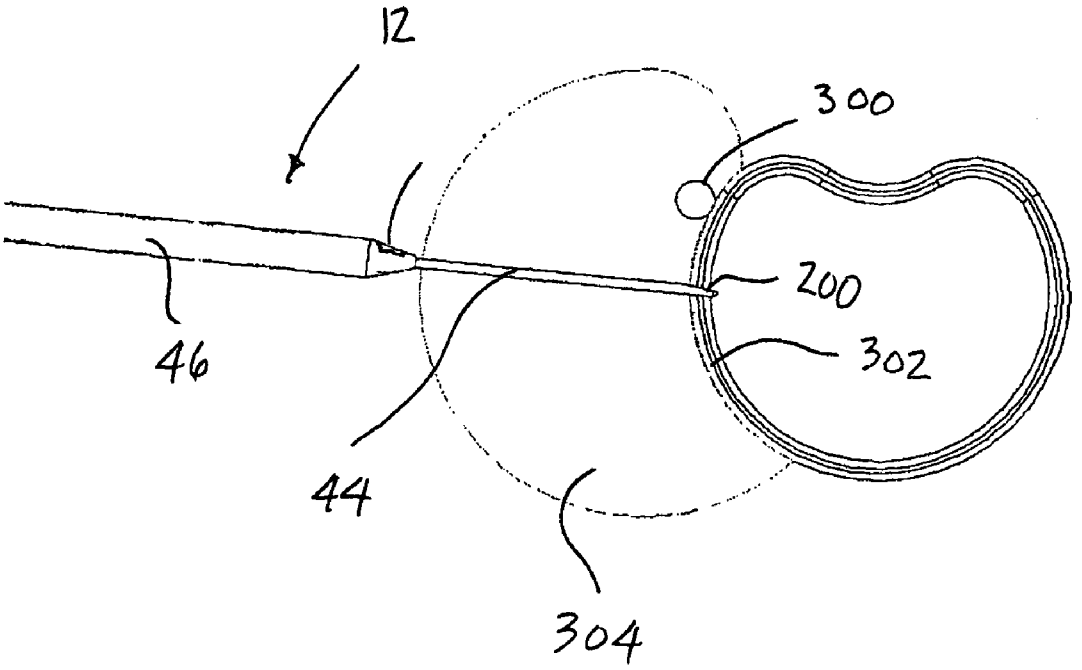



FIG. 17

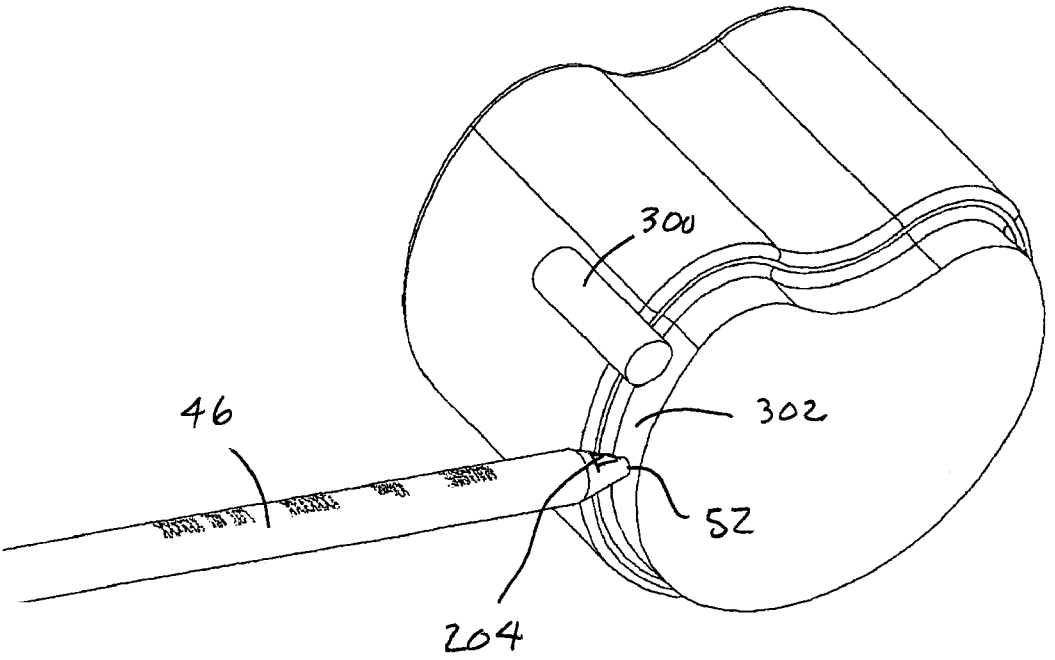



FIG. 18

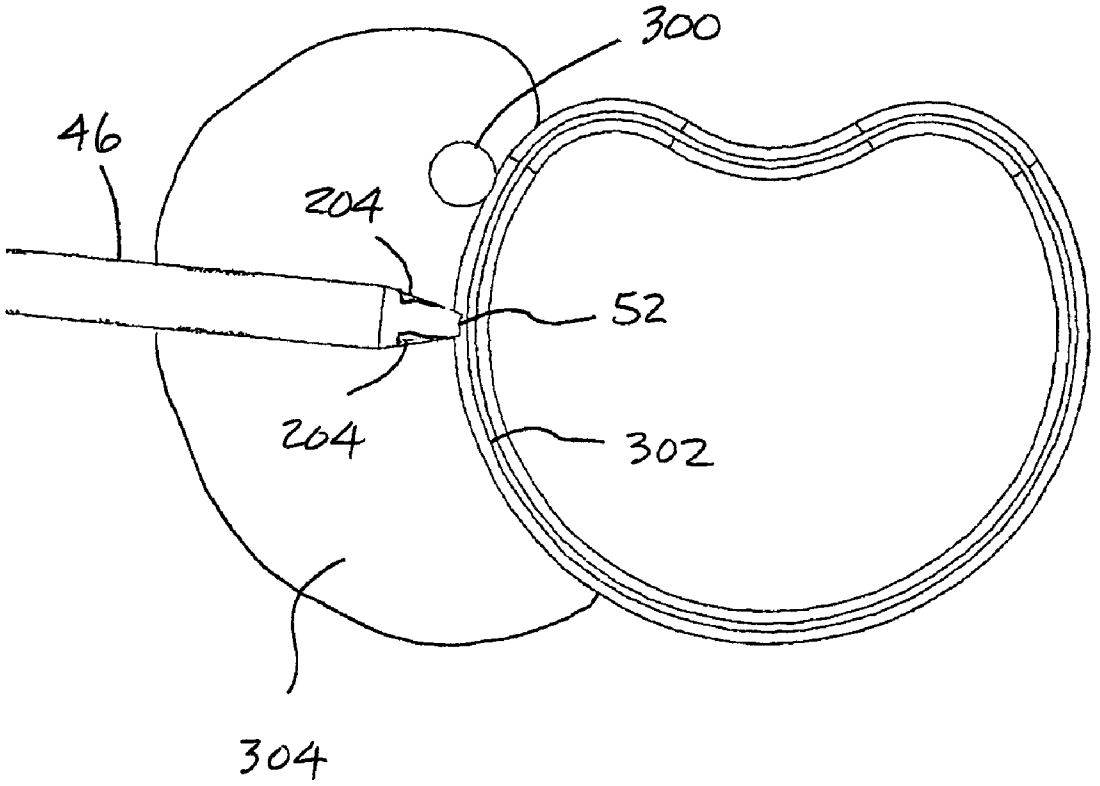



FIG. 19

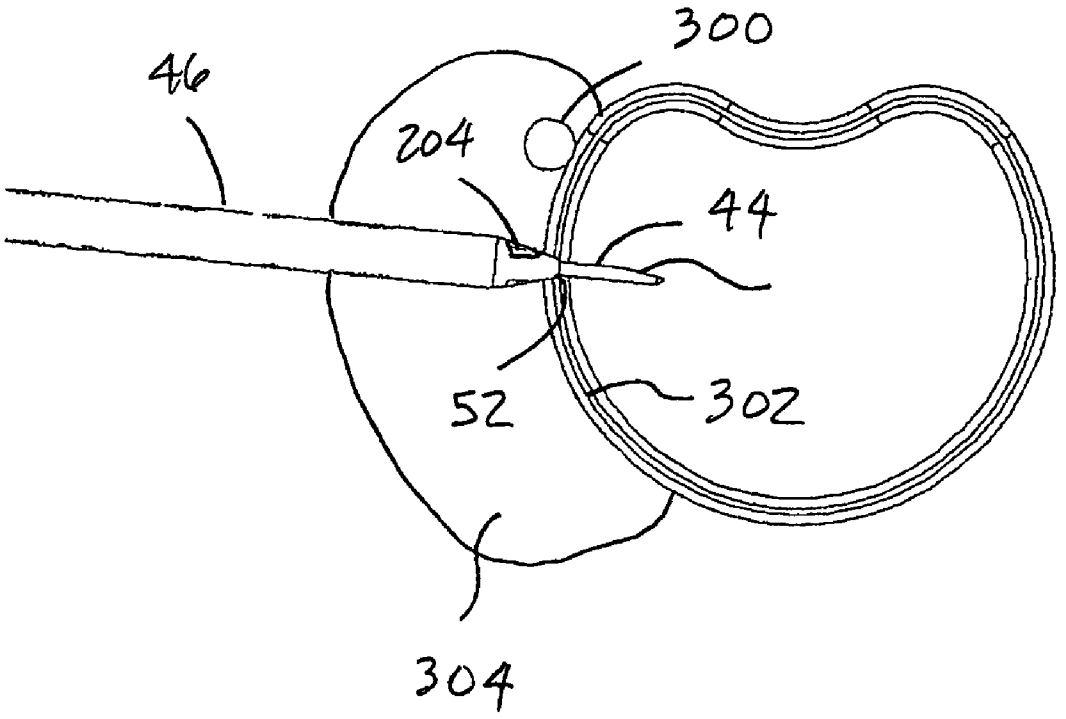
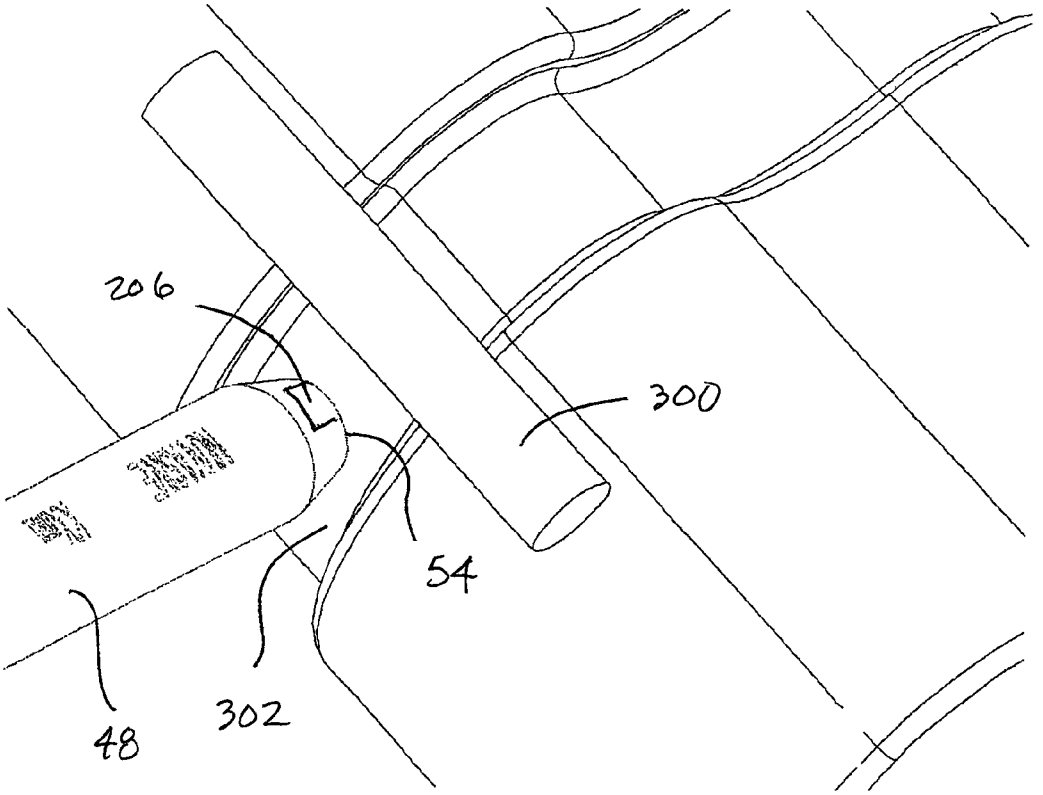



FIG. 20

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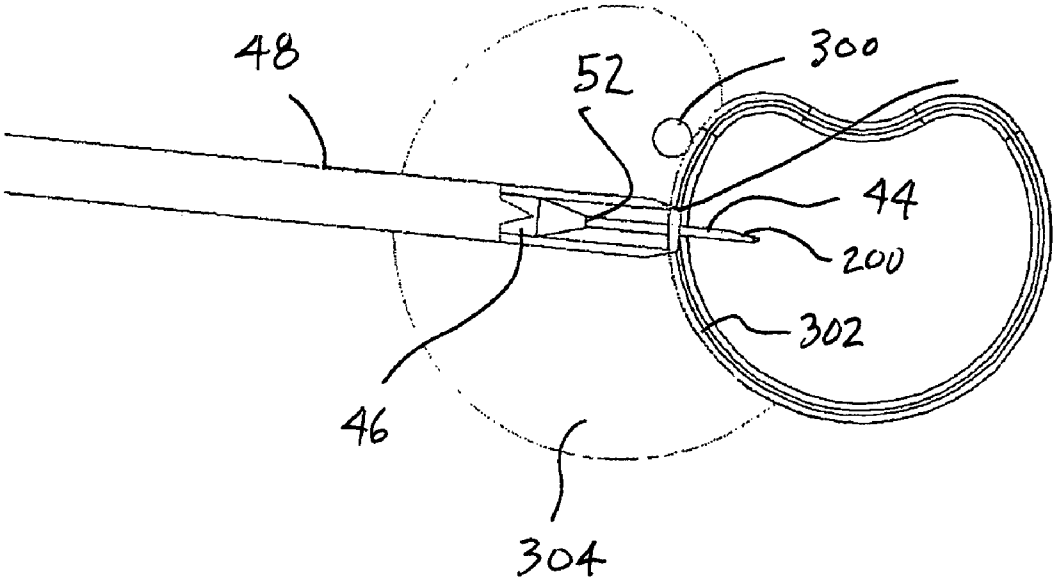



FIG. 22

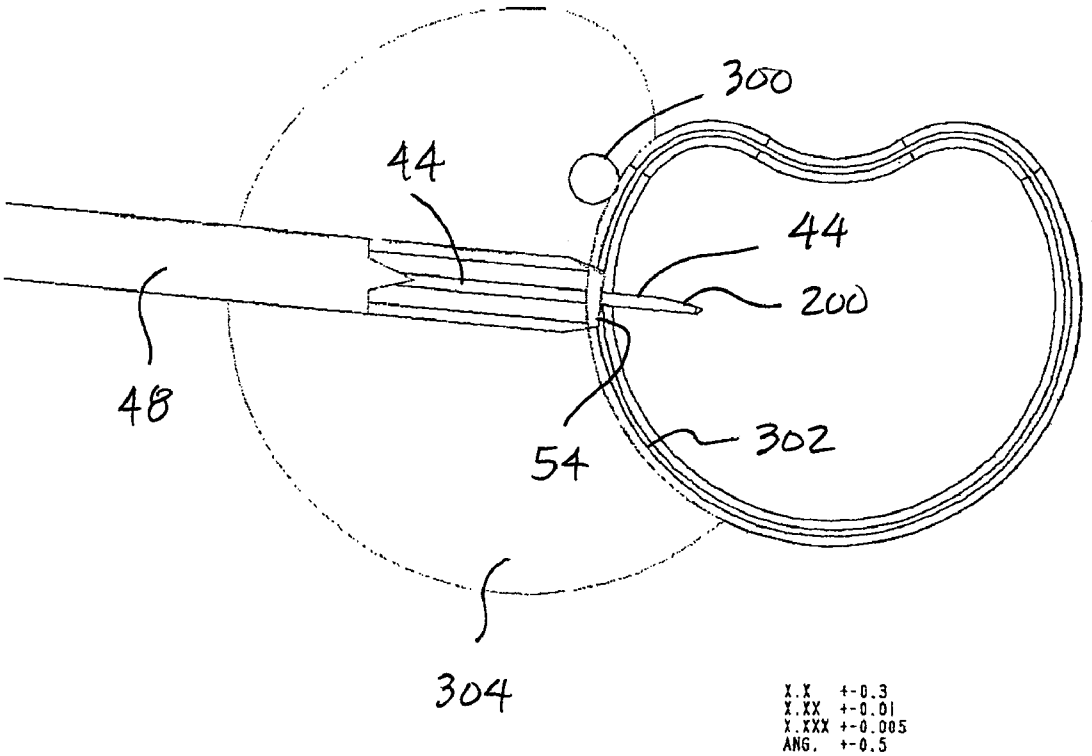



FIG. 23

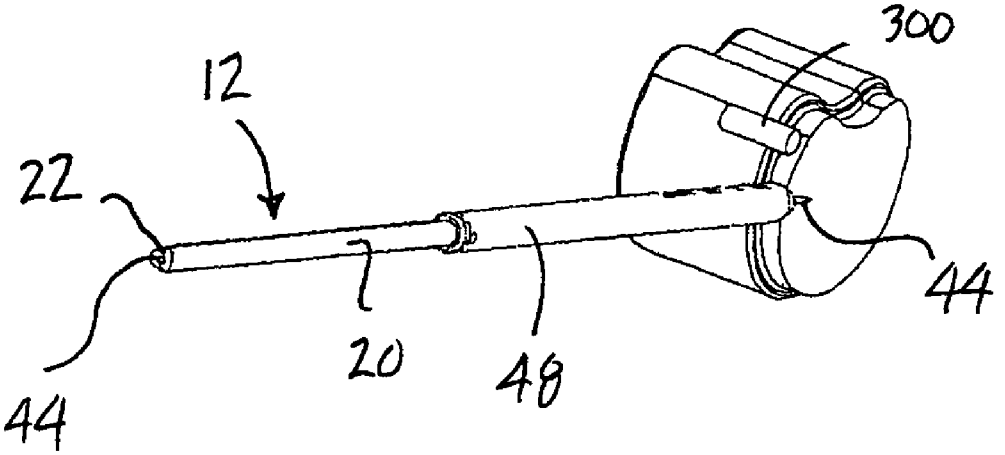
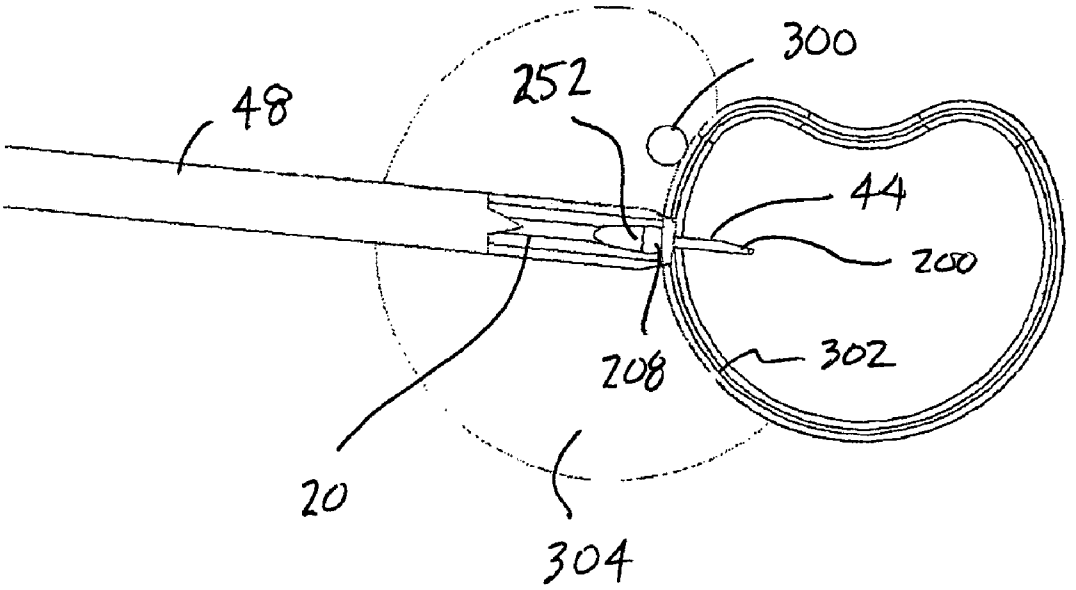



FIG. 24




X.X +-0.3
X.XX +-0.01
X.XXX +-0.005
ANG. +-0.5

FIG. 25

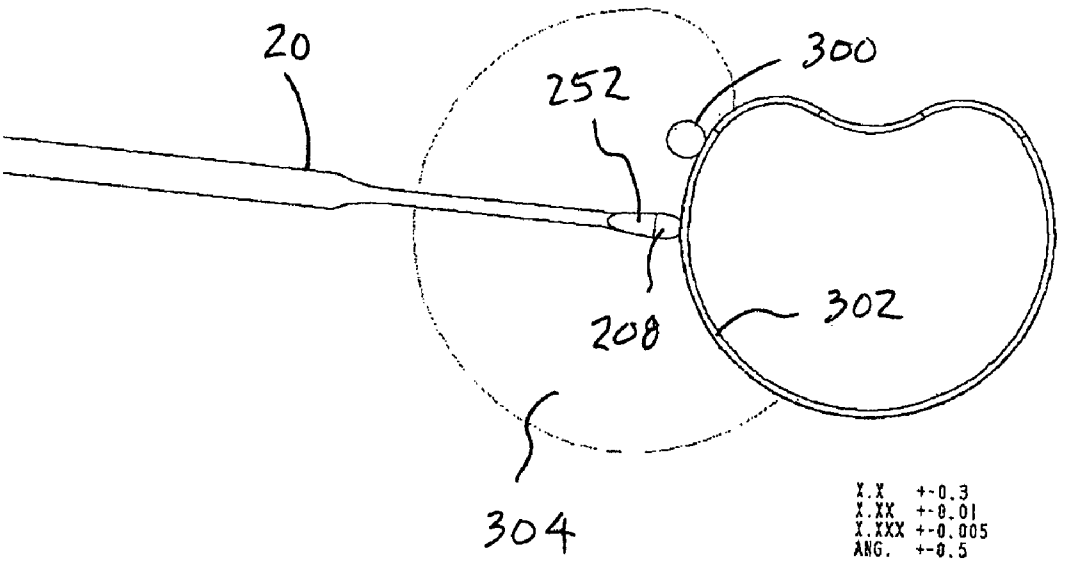



FIG. 26

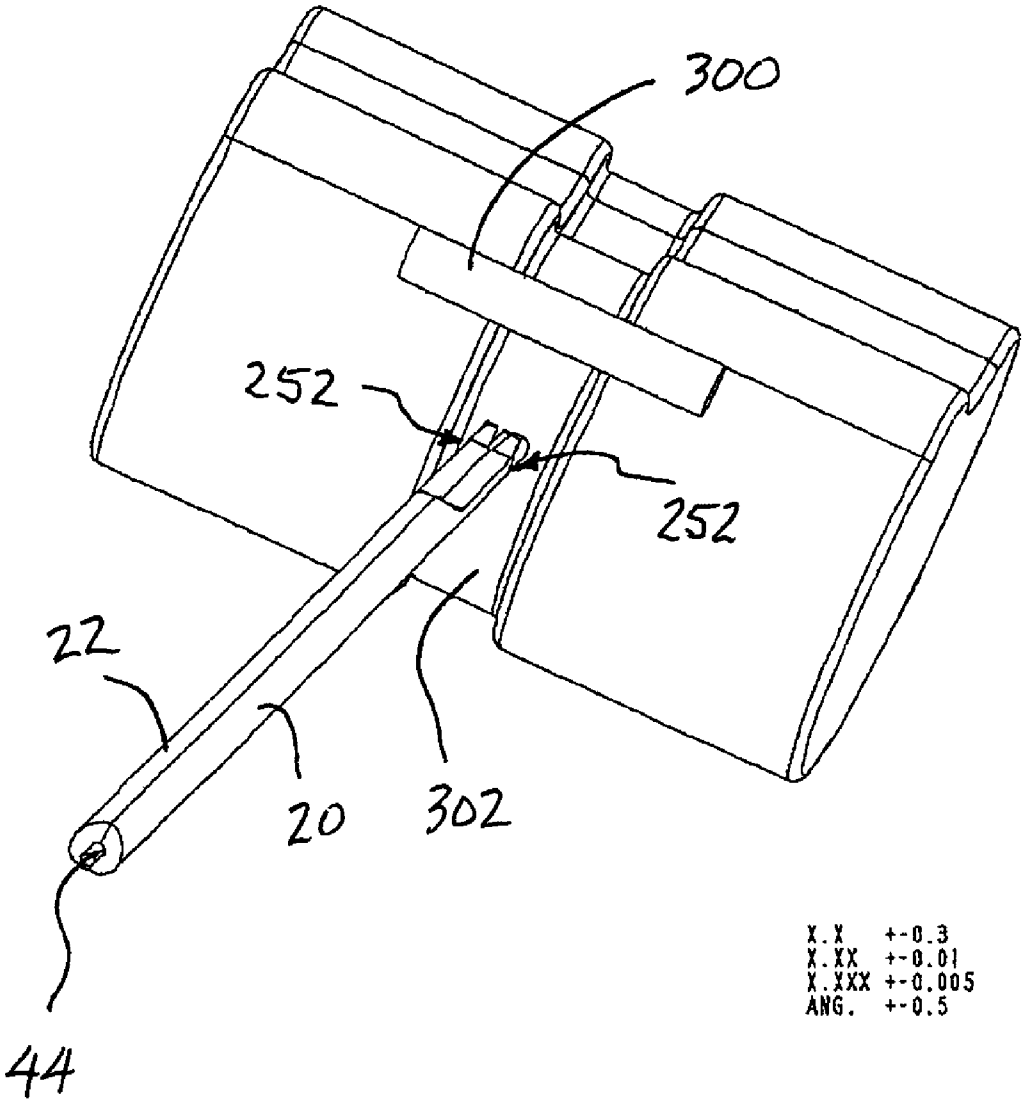



FIG. 27

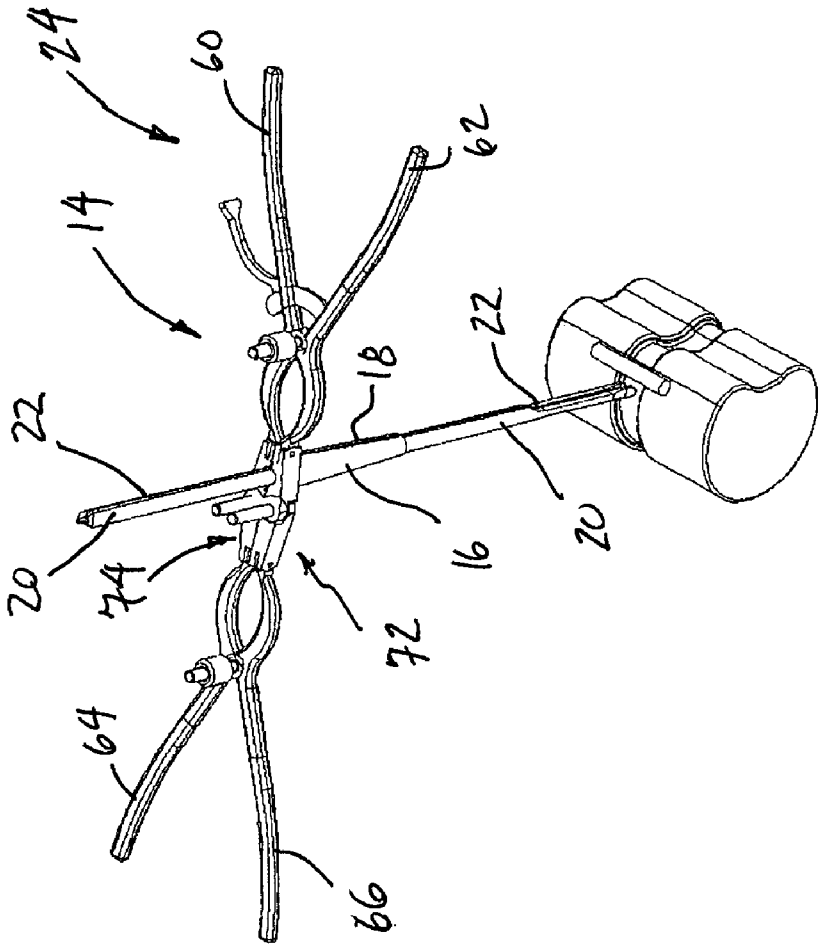



FIG. 28

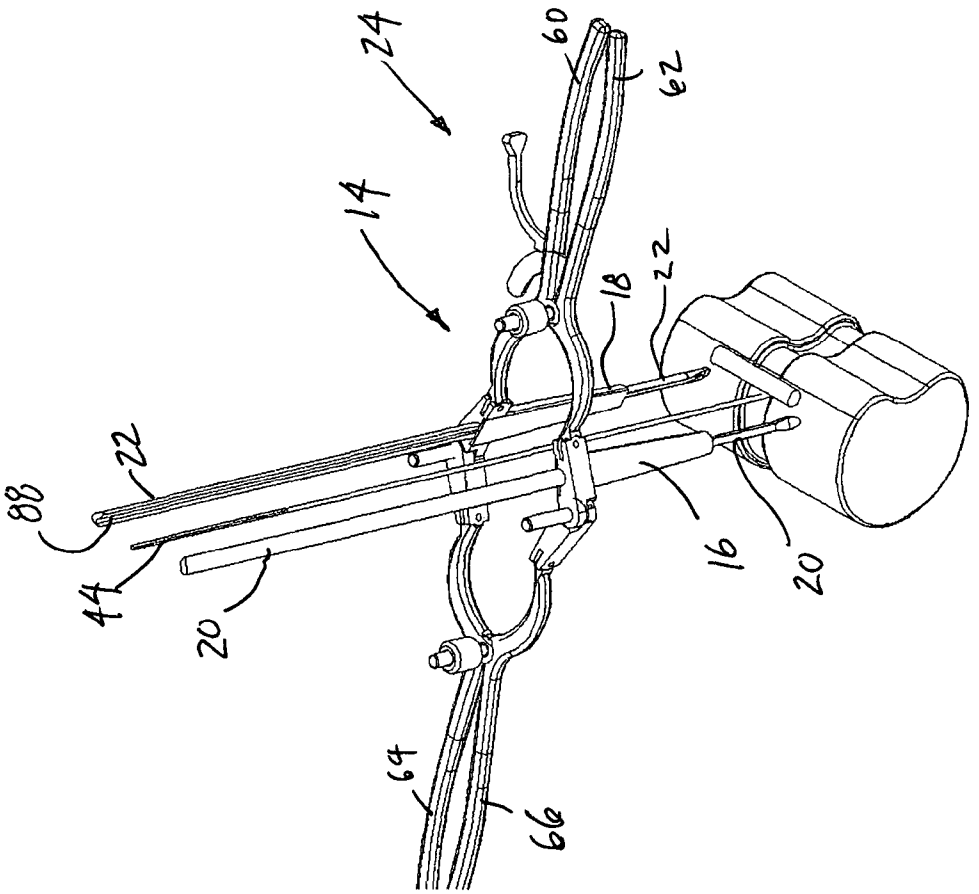



Fig. 29

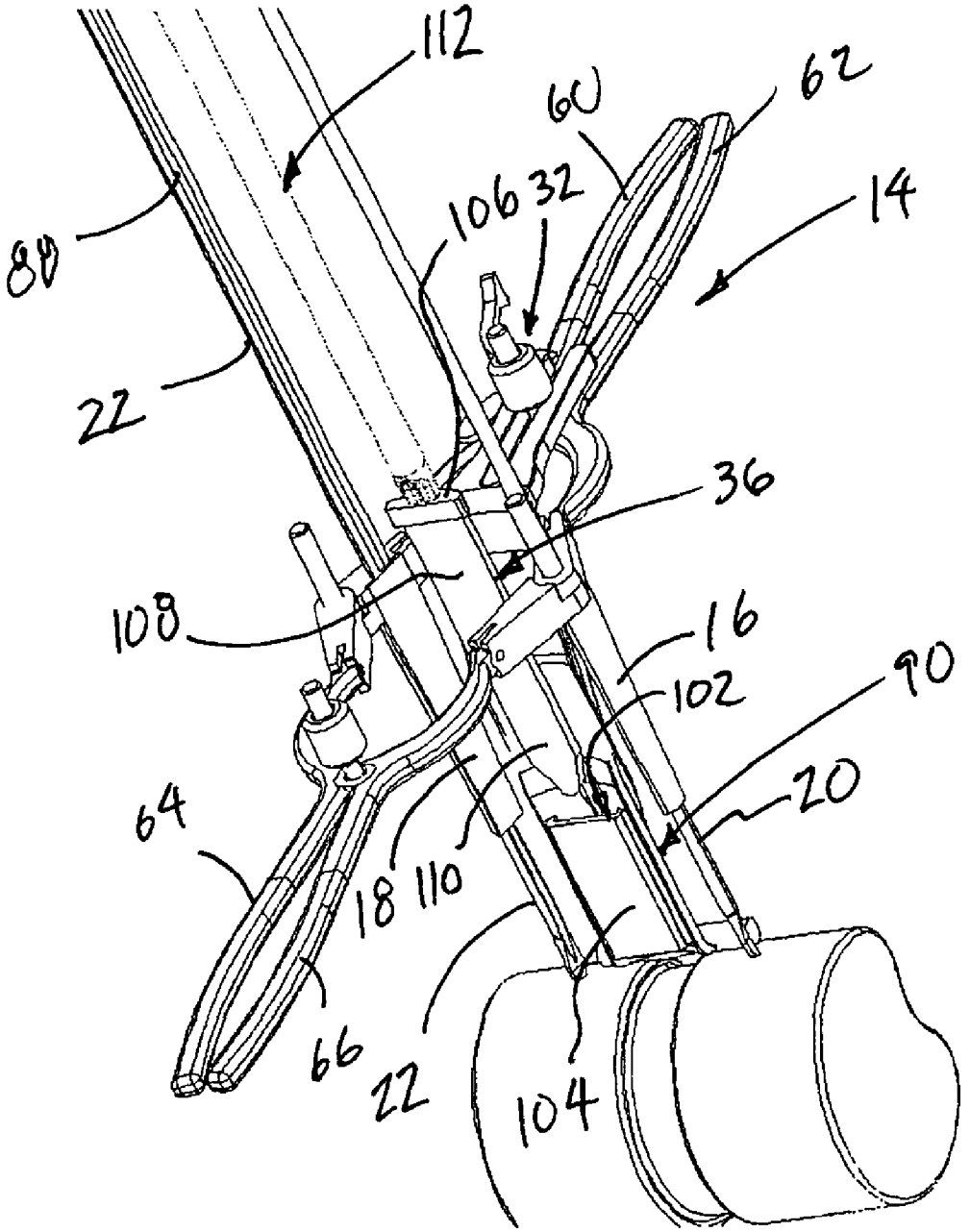



FIG. 30

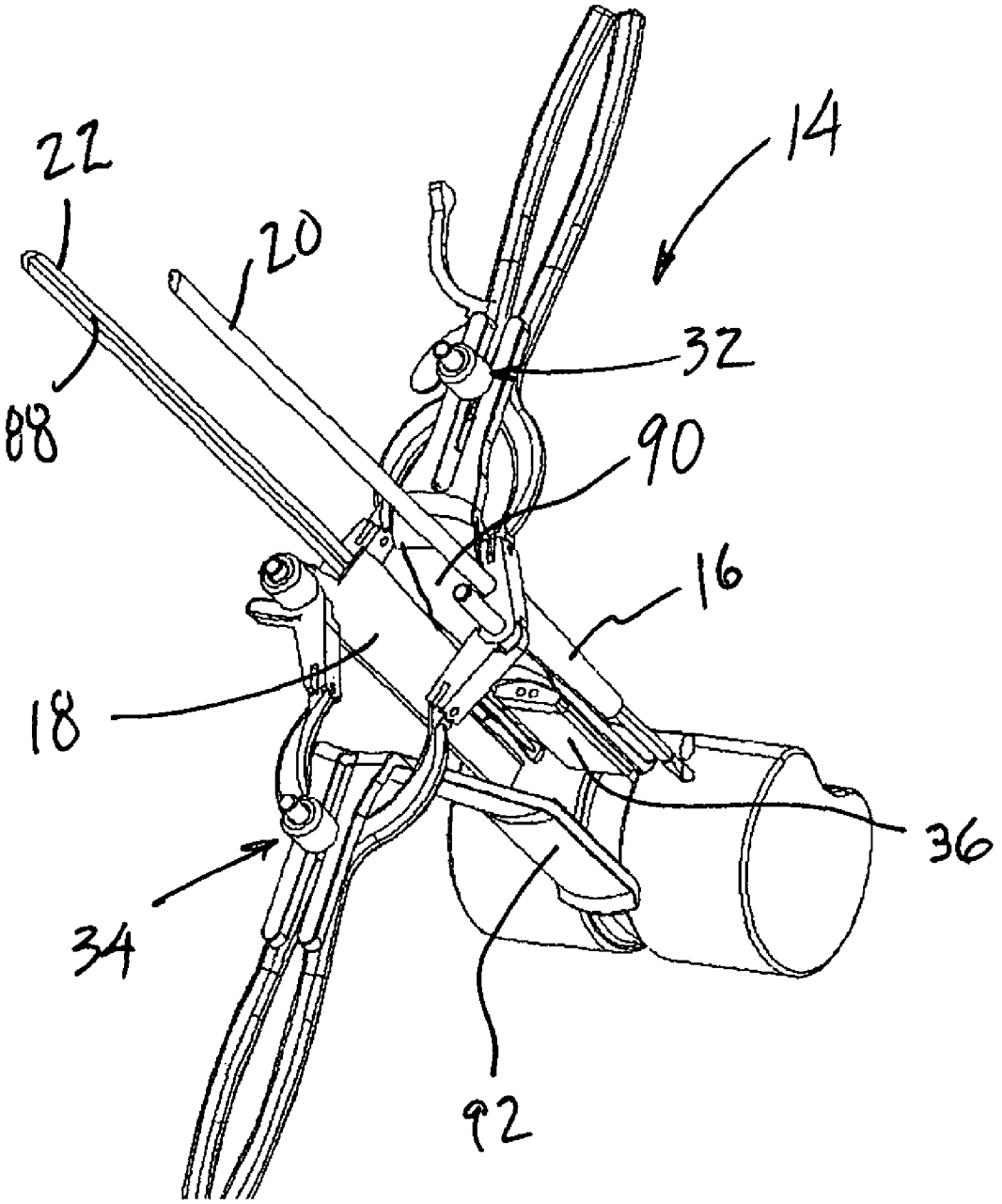



FIG. 31

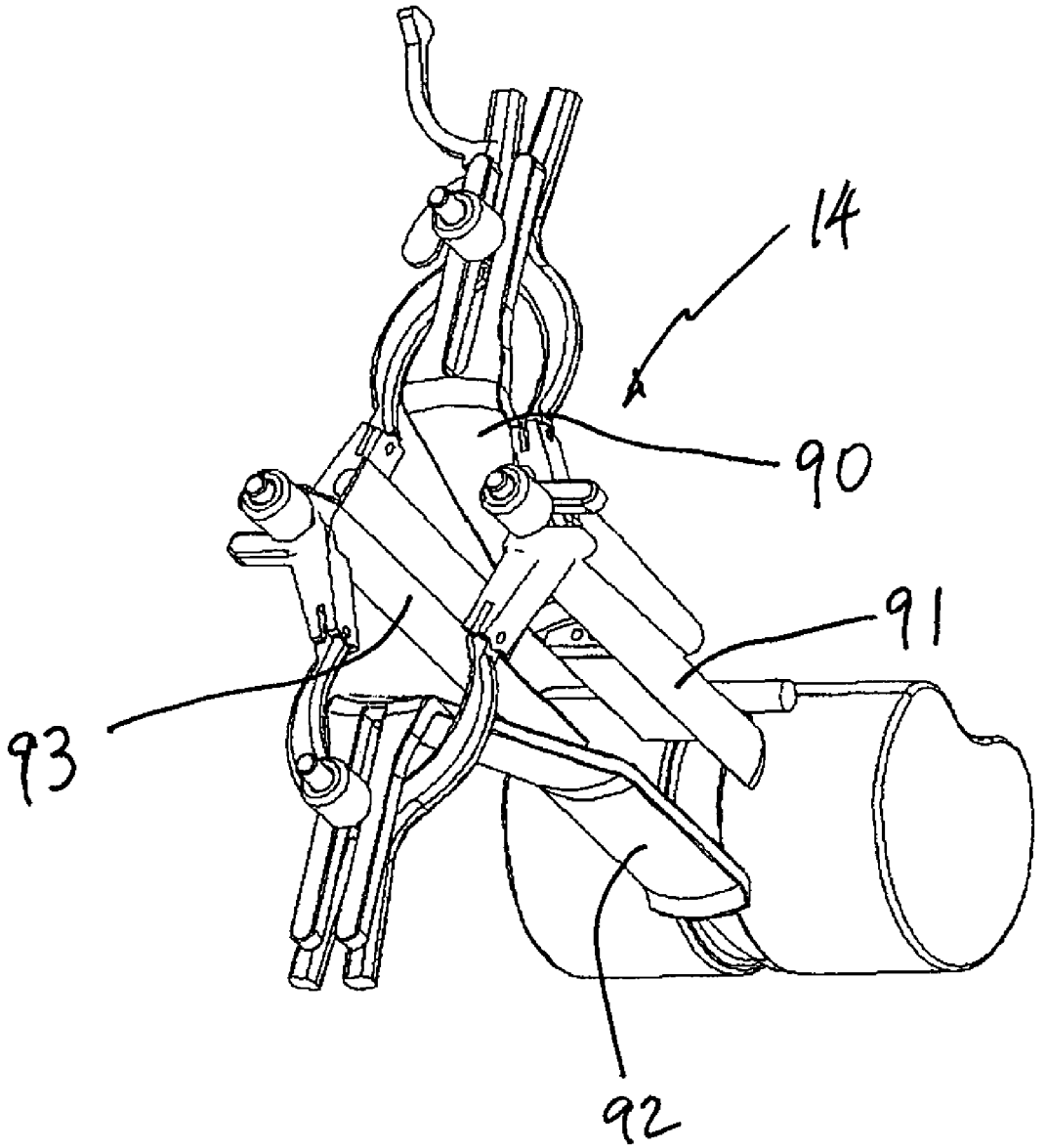



FIG. 32

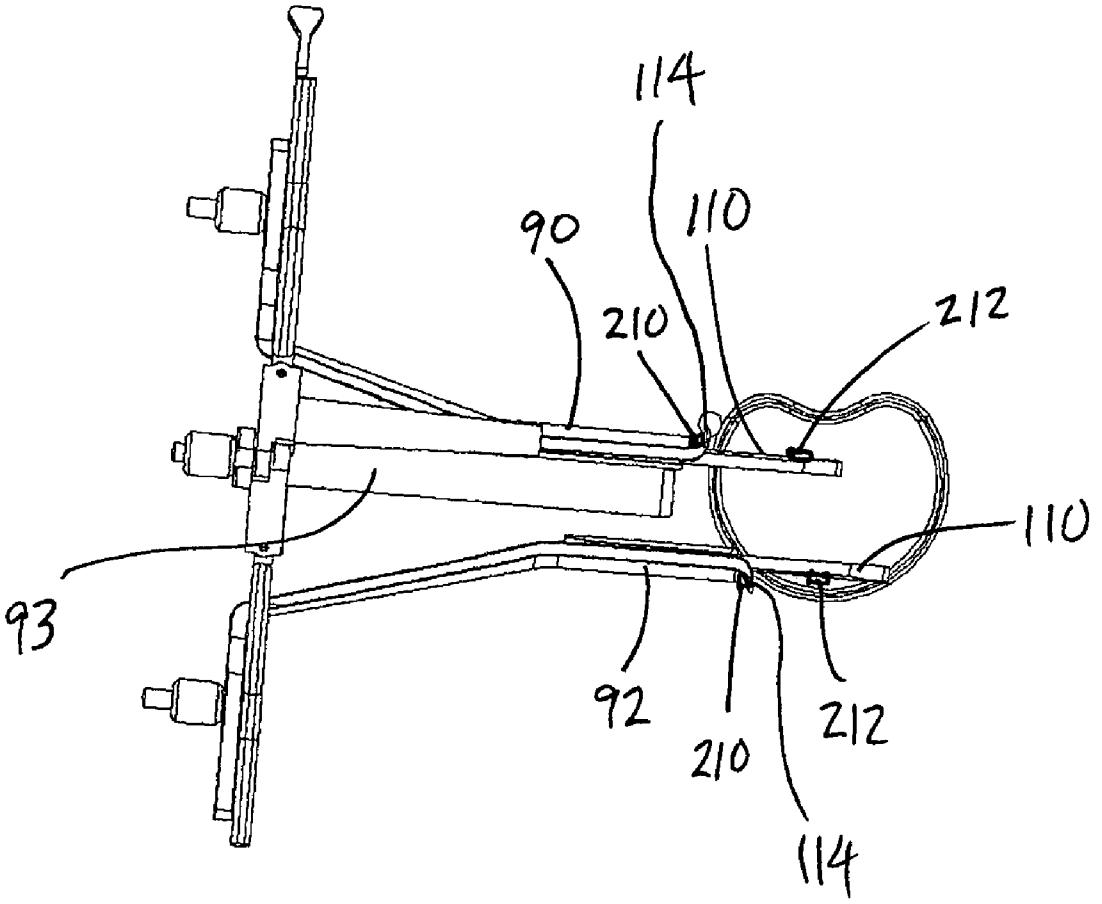



FIG. 33

# SURGICAL ACCESS SYSTEM AND RELATED METHODS

## CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is an International Patent Application of and claims the benefit of priority from commonly owned and co-pending U.S. Provisional Patent Application Ser. Nos. 60/392,214 (filed Jun. 26, 2002), the entire contents of which is hereby expressly incorporated by reference into this disclosure as if set forth fully herein. The present application also incorporates by reference the following co-pending and co-assigned patent applications in their entireties: PCT App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed on Jul. 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures and Assessments," filed on Sep. 25, 2002; PCT App. Ser. No. PCT/US02/35047, entitled "System and Methods for Performing Percutaneous Pedicle Integrity Assessments," filed on Oct. 30, 2002; and PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to a Surgical Instrument," filed Jan. 15, 2003.

## BACKGROUND

I. Field

The present invention relates generally to systems and methods for performing surgical procedures and, more particularly, for accessing a surgical target site in order to perform surgical procedures.

II. Description of Related Art

A noteworthy trend in the medical community is the move away from performing surgery via traditional "open" techniques in favor of minimally invasive or minimal access techniques. Open surgical techniques are generally undesirable in that they typically require large incisions and high amounts of tissue displacement to gain access to the surgical target site, which produces concomitantly high amounts of pain, lengthened hospitalization (increasing health care costs), and high morbidity in the patient population. Less-invasive surgical techniques (including so-called "minimal access" and "minimally invasive" techniques) are gaining favor due to the fact that they involve accessing the surgical target site via incisions of substantially smaller size with greatly reduced tissue displacement requirements. This, in turn, reduces the pain, morbidity and cost associated with such procedures. The access systems developed to date, however, fail in various respects to meet all the needs of the surgeon population.

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created, as well as maintained over time, depending upon the particular surgical target site. For example, when accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues). While certain efforts have been undertaken to reduce the trauma to tissue while creating an operative corridor, such as (by way of example only) the sequential dilation system of U.S. Pat. No. 5,792,044 to Foley et al., these attempts are nonetheless limited in their applicability based on the relatively narrow operative corridor. More



specifically, based on the generally cylindrical nature of the so-called "working cannula," the degree to which instruments can be manipulated and/or angled within the cannula can be generally limited or restrictive, particularly if the surgical target site is a relatively deep within the patient.

Efforts have been undertaken to overcome this drawback, such as shown in U.S. Pat. No. 6,524,320 to DiPoto, wherein an expandable portion is provided at the distal end of a cannula for creating a region of increased cross-sectional area adjacent to the surgical target site. While this system may provide for improved instrument manipulation relative to sequential dilation access systems (at least at deep sites within the patient), it is nonetheless flawed in that the deployment of the expandable portion may inadvertently compress or impinge upon sensitive tissues adjacent to the surgical target site. For example, in anatomical regions having neural and/or vasculature structures, such a blind expansion may cause the expandable portion to impinge upon these sensitive tissues and cause neural and/or vasculature compromise, damage and/or pain for the patient.

This highlights yet another drawback with the prior art surgical access systems, namely, the challenges in establishing an operative corridor through or near tissue having major neural structures which, if contacted or impinged, may result in neural impairment for the patient. Due to the threat of contacting such neural structures, efforts thus far have largely restricted to establishing operative corridors through tissue having little or substantially reduced neural structures, which effectively limits the number of ways a given surgical target site can be accessed. This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other procedures, posterior lumbar interbody fusion (PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

Posterior-access procedures involve traversing a shorter distance within the patient to establish the operative corridor, albeit at the price of oftentimes having to reduce or cut away part of the posterior bony structures (i.e. lamina, facets, spinous process) in order to reach the target site (which typically comprises the disc space). Anterior-access procedures are relatively simple for surgeons in that they do not involve reducing or cutting away bony structures to reach the surgical target site. However, they are nonetheless disadvantageous in that they require traversing through a much greater distance within the patient to establish the operative corridor, oftentimes requiring an additional surgeon to assist with moving the various internal organs out of the way to create the operative corridor.

The present invention is directed at eliminating, or at least minimizing the effects of, the above-identified drawbacks in the prior art.

## SUMMARY

The present invention accomplishes this goal by providing a novel access system and related methods which involve: (1) distracting the tissue between the patient's skin and the surgical target site to create an area of distraction (otherwise referred to herein as a "distraction corridor"); (2) retracting the distraction corridor to establish and maintain an operative corridor; and/or (3) detecting the existence of (and optionally the distance and/or direction to) neural structures before,

during and after the establishment of the operative corridor through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient.

As used herein, "distraction" or "distracting" is defined as the act of creating a corridor (extending to a location at or near the surgical target site) having a certain cross-sectional area and shape ("distraction corridor"), and "retraction" or "retracting" is defined as the act of creating an operative corridor by increasing the cross-sectional area of the distraction corridor (and/or modifying its shape) with at least one retractor blade and thereafter maintaining that increased cross-sectional area and/or modified shape such that surgical instruments can be passed through operative corridor to the surgical target site. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the access system of the present invention is suitable for use in any number of additional surgical procedures, including those wherein tissue having significant neural structures must be passed through (or near) in order to establish an operative corridor.

According to one aspect, the present invention provides a surgical access system having an initial tissue distraction assembly and a pivot linkage assembly forming part of a secondary distraction assembly and a retraction assembly. The secondary distraction assembly includes first and second distraction arms forming part of the pivot linkage assembly, first and second speculum blades extending through receiving passageways formed within the first and second distraction arms, and a handle assembly forming part of the pivot linkage. As will be described below, the distraction arms may be advanced over the initial distraction assembly such that the speculum blades are passed into the tissue to be secondarily distracted. Thereafter, the handle assembly may be activated to perform the necessary distraction. That is, the handle assembly can be manipulated by a user to move the first and second distraction arms away from one another, which will at the same time move the distal ends of the speculum blades to create a full distraction corridor.

After the secondary distraction, a pair of retractors blades may be introduced into the distraction corridor and positioned to create an operative corridor to the surgical target site. In a preferred embodiment, retractor blade is introduced first and positioned such that its distal end is generally located towards the posterior region of the spinal target site, which forms a useful barrier to prevent any exiting nerve roots **30** from entering the surgical target site, as well as to prevent any surgical instruments from passing outside the surgical target site and into contact with the exiting nerve roots **30** or other sensitive tissue. The retractor blade may thereafter be introduced and moved in a generally anterior direction away from the retractor blade, effectively creating the operative corridor. The retractor blades may be locked in relation to the pivot linkage assembly in any number of suitable fashions, including but not limited to the use of the nut-bolt assemblies well known in the art. To lock the retractor blades in relation to the surgical target site, optional locking members may be advanced through receiving passageways formed in one or more of the retractor blades such that a distal region of the locking member is brought into a press-fit, secure engagement between the adjacent vertebral bodies to thereby maintain the respective retractor blade in position. With the operative corridor established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated at or near the surgical target site depending upon the given surgical procedure.

According to yet another aspect of the present invention, any number of distraction assemblies and/or retraction assemblies (including but not limited to those described herein) may be equipped to detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. To accomplish this, one or more stimulation electrodes are provided on the various components of the distraction assemblies and/or retraction assemblies, a stimulation source (e.g. voltage or current) is coupled to the stimulation electrodes, a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards the surgical target site, and the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the nerves innervate, this indicates that neural structures may be in close proximity to the distraction and/or retraction assemblies.

This monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated with the neural structures likely to found in the tissue, as well as any number of monitoring systems. In either situation (traditional EMG or surgeon-driven EMG monitoring), the access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

## BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. **1** is a perspective view of a surgical access system according to one aspect of the present invention;

FIG. **2** is a perspective view of an initial tissue distraction assembly forming part of a surgical access system according to the present invention;

FIGS. **3-4** are exploded views detailing the distal portions of the initial tissue distraction assembly shown in FIG. **2**;

FIG. **5** is a perspective view of a pivot linkage assembly equipped with speculum blades according to the present invention;

FIG. **6** is a side view of the pivot linkage assembly shown in FIG. **5**;

FIGS. **7-8** are perspective views showing the pivot linkage assembly of FIG. **5** in use;

FIGS. **9-10** are perspective views of a retractor blade forming part of a surgical access system according to the present invention;

FIG. **11** is a perspective view of a locking member for use with the retractor blade of FIGS. **9-10** according to the present invention;

FIG. **12** is a perspective view of an exemplary nerve monitoring system capable of performing nerve monitoring before, during and after the creating of an operative corridor to a surgical target site using the surgical access system in accordance with the present invention;

FIG. **13** is a block diagram of the nerve monitoring system shown in FIG. **12**;

FIGS. **14-15** are screen displays illustrating exemplary features and information communicated to a user during the use of the nerve monitoring system of FIG. **12**;

FIGS. **16-33** illustrate the various method steps (some optional) involved in accessing (by way of example only) a surgical target site in the spine according to the present invention.

## DETAILED DESCRIPTION

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. It is furthermore to be readily understood that, although discussed below primarily within the context of spinal surgery, the surgical access system of the present invention may be employed in any number of anatomical settings to provide access to any number of different surgical target sites throughout the body. The surgical access system disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

The present invention is directed at a novel surgical access system and related methods which involve creating a distraction corridor to a surgical target site, thereafter retracting the distraction corridor to establish and maintain an operative corridor to the surgical target site, and optionally detecting the existence of (and optionally the distance and/or direction to) neural structures before, during and/or after the formation of the distraction and/or operative corridors. The steps of distraction followed by retraction are advantageous because they provide the ability to more easily position an operative corridor-establishing device through tissue that is strong, thick or otherwise challenging to traverse in order to access a surgical target site. The various distraction systems of the present invention are advantageous in that they provide an improved manner of atraumatically establishing a distraction corridor prior to the use of the retraction systems of the present invention. The various retractor systems of the present invention are advantageous in that they provide an operative corridor having improved cross-sectional area and shape (including customization thereof) relative to the prior art surgical access systems. Moreover, by optionally equipping the various distraction systems and/or retraction systems with one or more electrodes, an operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient.

FIG. **1** illustrates a surgical access system **10** according to one aspect of the present invention. The surgical access system **10** includes an initial tissue distraction assembly **12** and a pivot linkage assembly **14** forming part of a secondary distraction assembly and a retraction assembly. The secondary distraction assembly includes first and second distraction arms **16**, **18** forming part of the pivot linkage assembly **14**, first and second speculum blades **20**, **22** extending through receiving passageways formed within the first and second distraction arms **16**, **18**, and a handle assembly **24** forming part of the pivot linkage **14**. As will be described below, the distraction arms **16**, **18** may be advanced over the initial distraction assembly **12** such that the speculum blades **20**, **22** are passed into the tissue to be secondarily distracted. Thereafter, the handle assembly **24** may be activated to perform the necessary distraction. That is, the handle assembly **24** can be manipulated by a user to move the first and second distraction arms **16**, **18** away from one another, which will at the same time move the distal ends of the speculum blades **20**, **22** to create a full distraction corridor.

After the secondary distraction, a pair of retractors blades **26**, **28** may be introduced into the distraction corridor and positioned to create an operative corridor to the surgical target site. In a preferred embodiment, retractor blade **26** is introduced first and positioned such that its distal end is generally located towards the posterior region of the spinal target site, which forms a useful barrier to prevent any exiting nerve roots **30** from entering the surgical target site, as well as to prevent any surgical instruments from passing outside the surgical target site and into contact with the exiting nerve roots **30** or other sensitive tissue. The retractor blade **28** may thereafter be introduced and moved in a generally anterior direction away from the retractor blade **26**, effectively creating the operative corridor. The retractor blades **26**, **28** may be locked in relation to the pivot linkage assembly **14** in any number of suitable fashions, including but not limited to the use of the nut-bolt assemblies **32**, **34** well known in the art. To lock the retractor blades **26**, **28** in relation to the surgical target site, optional locking members **36** may be advanced through receiving passageways formed in one or more of the retractor blades **26**, **28** such that a distal region of the locking member **36** is brought into a press-fit, secure engagement between the adjacent vertebral bodies to thereby maintain the respective retractor blade **26**, **28** in position. With the operative corridor established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated at or near the surgical target site depending upon the given surgical procedure.

### Distraction

FIG. **2** illustrates the initial tissue distraction assembly **12**, which is designed to perform an initial distraction of tissue from the skin of the patient down to or near the surgical target site. The initial tissue distraction assembly **12** may be constructed from any number of materials suitable for medical applications, including but not limited to plastics, metals, ceramics or any combination thereof. Depending on the construction, some or all of the tissue distraction assembly **12** may be disposable (i.e. single use) and/or reusable (i.e. multi-use).

The initial tissue distraction assembly **12** may include any number of components capable of performing the necessary initial distraction. By way of example, with combined reference to FIGS. **2-4**, this may be accomplished by providing the initial distraction assembly **12** as including a K-wire **44** and one or more dilators **46**, **48**. The K-wire **44** is preferably constructed having generally narrow diameter (such as, by way of example only, 1.5 mm) and sufficient rigidity and strength such that it can pierce the skin of the patient and be advanced through the intervening tissue to reach the surgical target site. The K-wire **44** also preferably includes indicia for determining the distance between a distal end **50** and the skin of the patient. The dilators **46**, **48** are inner and outer dilating elements, respectively, capable of being sequentially introduced over the K-wire **44** for the purpose of further distracting the tissue previously distracted by the K-wire **44**.

The inner dilator **46** is preferably constructed having an inner diameter approximating the diameter of the K-wire **44** (such as, by way of example only, 1.5 mm), an outer diameter

of increased dimension (such as, by way of example only, 6.5 mm), and indicia for determining the distance between a distal end **52** and the skin of the patient. The outer dilator **48** is similarly preferably constructed having an inner diameter approximating the outer diameter of the inner dilator **46** (such as, by way of example only, 6.5 mm), an outer diameter of increased dimension (such as, by way of example only, 9 mm), and indicia for determining the distance between a distal end **54** and the skin of the patient. The respective lengths of the K-wire **44** and dilators **46**, **48** may vary depending upon the given surgical target site (that is, the "depth" of the surgical target site within the patient). It will be similarly appreciated that the diameters and dimensions for these elements may also vary depending upon the particular surgical procedure. All such surgically appropriate variations (length, diameter, etc. . . . ) are contemplated as falling within the scope of the present invention. It is further contemplated and within the scope of the present invention that additional dilators of increasing diameters may be employed to sequentially dilate to the point where a bladed retractor or retraction assembly may be employed to thereafter create an operative corridor according to the present invention (without the need for secondary distraction as described below).

Referring to FIGS. **5-6**, the secondary tissue distraction is preferably performed using the pivot linkage assembly **14** in conjunction with the first and second distraction arms **16**, **18** and first and second speculum blades **20**, **22**. The speculum blades **20**, **22** extend through receiving passageways **38** (FIG. **6**) formed within the first and second distraction arms **16**, **18**. The handle assembly **24** includes first and second pivot arms **60**, **62** disposed on one end of the assembly, and third and fourth pivot arms **64**, **66** on the opposite end. First and second pivot arms **60**, **62** are pivotably coupled via a rod **80** forming part of the locking assembly **32** (a locking nut **82** forms the remainder of the locking assembly **32**). Second and third pivot arms **64**, **66** are pivotably coupled via a rod **84** forming part of the locking assembly **34** (a locking nut **86** forms the remainder of the locking assembly **34**).

First and second linkage assemblies **70**, **72** extend between the distal ends of the pivot arms **60-66**, each including a pair of linkages **74**, **76** pivotably coupled together via a rod **78**. A ratchet member **68** may be used to maintain the first pivot arms **60** relative to the second pivot arm **62** as they are separated during use. As the pivot arms **60**, **62** are moved away from one another, the first and second distraction arms **16**, **18** (being coupled to or integrally formed with the linkages **76** of first and second linkage assemblies **72**, **74**) will similarly move away from one another. With the speculum blades **20**, **22** disposed within the passageways **38** (FIG. **5**), the relative movement of the pivot arms **16**, **18** will cause the speculum blades **20**, **22** to move apart and thus perform the desired secondary distraction.

The pivot linkage assembly **14** may be constructed from any number of materials suitable for medical applications, including but not limited to plastics, metals, ceramics or any combination thereof. Depending on the construction, some or all of the pivot linkage assembly **14** may be disposable (i.e. single use) and/or reusable (i.e. multi-use).

The speculum blades **20**, **22** are generally elongate in nature and include a pair of mating grooves **88** formed along the inwardly facing surfaces of the speculum blades **20**, **22** which, when mated together, form a lumen capable of passing over the K-wire **44**. In a preferred embodiment, the speculum blades **20**, **22** are separable from distraction arms **16**, **18** such that the blades **20**, **22** can be introduced into the patient and thereafter engaged with the handle assembly **24** to effectuate the secondary distraction. As will be described in greater detail below, this separable construction allows the speculum blades **20**, **22** to be introduced down to the surgical target site by passing them through the outer dilator **48** and over with the K-wire **44** (the latter by virtue of the lumen formed by the pair of mating grooves **88** along the inwardly facing surfaces of the speculum blades **20**, **22**). This is obviously only possible by first removing the inner dilator **46** from within the second dilator **48** while leaving the K-wire **44** in place. Although shown and described herein as being of separable construction, it will be appreciated by those skilled in the art that the speculum blades **20**, **22** may be of generally non-separable or fixed construction with the pivot arms **16**, **18** of the handle assembly **24**.

Retraction

The retraction of the present invention is performed by expanding and/or modifying the distraction corridor to establish and maintain an operative corridor to the surgical target site. As shown in FIGS. **7-10**, the pivot linkage **14** is configured to receive (and have coupled thereto) a pair of retractor blades **90**, **92** of the type shown in FIGS. **9-10**. The retractor blades **90**, **92** include a main body element **94** extending downwardly and angularly away from a pair of mounting arms **96**, **98**. The mounting arms **96**, **98** are spaced apart from one another so as to create a channel **100** dimensioned to receive the respective rods **80**, **84** of the locking assemblies **32**, **34**. Once positioned within the channel **100**, the retractor blades **90**, **92** may be locked in a desired position by tightening the respective nuts **82**, **86** of the locking assemblies **32**, **34**.

In a preferred embodiment, one or more of the retractor blades **90**, **92** may be equipped with a passageway **102** at or near the distal end of the main body **94**, such as by providing a generally planar member **104** along the generally curved distal region of the retractor blade **90**, **92**. This passageway **102** is dimensioned to receive a locking member **36** of the type shown in FIG. **11**. The locking member **36** includes a coupling region **106** for engagement with an introducer tool **112** (FIG. **8**), a main body region **108** to be disposed generally within the passageway **102** in use, and a distal region **110** to be introduced into the disc space and engaged between the adjacent vertebral bodies to secure the distal ends of the retractor blades **90**, **92** during use. In addition to securing the retractor blades **90**, **92** relative to the surgical target site, the distal region **110** also serves to prevent the ingress of unwanted or sensitive biological structures (e.g., nerve roots and/or vasculature) into the surgical target site, as well as prevent instruments from passing outside the surgical target site and contacting surrounding tissues or structures.

The retractor blades **90**, **92** may also be optionally provided with at least one guard member **114** extending in a curved fashion (and/or, although not shown, in a generally straight fashion) from the distal end of the retractor blade **90**, **92**. The guard member **114** may be provided, by way of example, for the purpose of preventing tissue (such as nerve roots in spinal surgery applications) from entering into the operative corridor during surgery and for preventing instruments from extending outside the operative corridor and/or the general vicinity of the surgical target site.

The retractor blades **90**, **92** may also be equipped with any number of different mechanisms for transporting or emitting light at or near the surgical target site to aid the surgeon's ability to visualize the surgical target site, instruments and/or implants during the given surgical procedure. For example, one or more strands of fiber optic cable may be coupled to the retractor blades **90**, **92** such that light may be delivered from a light source and selectively emitted into the operative cor-

ridor and/or the surgical target site. This may be accomplished by constructing the retractor blades **90**, **92** of suitable material (such as clear polycarbonate) and configuration such that light may be transmitted generally distally through a light exit region formed along the entire inner periphery of the retractor blade **90**, **92** and located in the general vicinity as the distal opening of the passageway **102**. This may be performed by providing the retractor blade **90**, **92** having light-transmission characteristics (such as with clear polycarbonate construction) and transmitting the light almost entirely within the walls of the retractor blade **90**, **92** (such as by frosting or otherwise rendering opaque portions of the exterior and/or interior and coupling the light source thereto such as via a port) until it exits a portion along the interior of the retractor blades **90**, **92** to shine at or near the surgical target site.

In one embodiment, a variety of sets of retractor blades **90**, **92** may be provided, each having a different length to account for any number of possible surgical target sites. In a further embodiment, each set of retractor blades **90**, **92** may be marked or color-coded to aid in indicating to the surgeon the particular length of the blade **90**, **92** or the depth of the surgical target site.

The retractor blades **90**, **92** and the locking member **36** may be constructed from any number of materials suitable for medical applications, including but not limited to plastics, metals, ceramics or any combination thereof. Depending on the construction, some or all of these devices may be disposable (i.e. single use) and/or reusable (i.e. multi-use).

Any number of suitable mounting units (not shown) may be employed to maintain the pivot linkage assembly **14** in a fixed and rigid fashion relative to the patient. By way of example only, this may be accomplished by providing the mounting unit as a generally U-shaped mounting arm for lockable engagement with the pivot linkage assembly **14**, and a coupling mechanism (not shown) extending between the mounting arm and a rigid structure (such as the operating table) for maintaining the U-shaped mounting arm in a fixed and rigid position.

## Nerve Surveillance

According to yet another aspect of the present invention, any number of distraction components and/or retraction components (including but not limited to those described herein) may be equipped to detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. This is accomplished by employing the following steps: (1) one or more stimulation electrodes are provided on the various distraction and/or retraction components; (2) a stimulation source (e.g. voltage or current) is coupled to the stimulation electrodes; (3) a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards or maintained at or near the surgical target site; and (4) the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the nerves innervate, this may indicate that neural structures may be in close proximity to the distraction and/or retraction components.

Neural monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated with the neural structures likely to found in the tissue, as well as any number of monitoring systems, including but not limited to any commercially available "traditional" electromyography (EMG) system (that is, typically operated by a neurophysiologist. Such monitoring may also be carried out via the surgeon-driven EMG monitoring system shown and described in the following commonly owned and co-pending PCT Applications (collectively "NeuroVision PCT Applications"): PCT App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed on Jul. 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures and Assessments," filed on Sep. 25, 2002; PCT App. Ser. No. PCT/US02/35047, entitled "System and Methods for Performing Percutaneous Pedicle Integrity Assessments," filed on Oct. 30, 2002; and PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to a Surgical Instrument," filed Jan. 15, 2003. The entire contents of each of the above-enumerated NeuroVision PCT Applications is hereby expressly incorporated by reference into this disclosure as if set forth fully herein.

In any case (visual monitoring, traditional EMG and/or surgeon-driven EMG monitoring), the access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

FIGS. **12-13** illustrate, by way of example only, a monitoring system **120** of the type disclosed in the NeuroVision PCT Applications suitable for use with the surgical access system **10** of the present invention. The monitoring system **120** includes a control unit **122**, a patient module **124**, and an EMG harness **126** and return electrode **128** coupled to the patient module **124**, and a cable **132** for establishing electrical communication between the patient module **124** and the surgical access system **10** (FIG. **1**). More specifically, this electrical communication can be achieved by providing, by way of example only, a hand-held stimulation controller **152** capable of selectively providing a stimulation signal (due to the operation of manually operated buttons on the hand-held stimulation controller **152**) to one or more connectors **156***a*, **156***b*, **156***c*. The connectors **156***a*, **156***b*, **156***c* are suitable to establish electrical communication between the hand-held stimulation controller **152** and (by way of example only) the stimulation electrodes on the K-wire **44**, the dilators **46**, **46**, the speculum blades **20**, **22**, the retractor blades **90**, **92**, and/or the guard members **114** (collectively "surgical access instruments").

In order to use the monitoring system **120**, then, these surgical access instruments must be connected to the connectors **156***a*, **156***b* and/or **156***c*, at which point the user may selectively initiate a stimulation signal (preferably, a current signal) from the control unit **122** to a particular surgical access instruments. Stimulating the electrode(s) on these surgical access instruments before, during and/or after establishing operative corridor will cause nerves that come into close or relative proximity to the surgical access instruments to depolarize, producing a response in a myotome associated with the innervated nerve.

The control unit **122** includes a touch screen display **140** and a base **142**, which collectively contain the essential processing capabilities (software and/or hardware) for controlling the monitoring system **120**. The control unit **122** may include an audio unit **118** that emits sounds according to a location of a surgical element with respect to a nerve. The patient module **124** is connected to the control unit **122** via a data cable **144**, which establishes the electrical connections and communications (digital and/or analog) between the control unit **122** and patient module **124**. The main functions of the control unit **122** include receiving user commands via the

touch screen display **140**, activating stimulation electrodes on the surgical access instruments, processing signal data according to defined algorithms, displaying received parameters and processed data, and monitoring system status and report fault conditions. The touch screen display **140** is preferably equipped with a graphical user interface (GUI) capable of communicating information to the user and receiving instructions from the user. The display **140** and/or base **142** may contain patient module interface circuitry (hardware and/or software) that commands the stimulation sources, receives digitized signals and other information from the patient module **124**, processes the EMG responses to extract characteristic information for each muscle group, and displays the processed data to the operator via the display **140**.

In one embodiment, the monitoring system **120** is capable of determining nerve direction relative to one or more of the K-wire **44**, dilation cannula **46**, **48**, speculum blades **20**, **22**, the retractor blades **90**, **92**, and/or the guard members **114** before, during and/or following the creation of an operative corridor to a surgical target site. Monitoring system **120** accomplishes this by having the control unit **122** and patient module **124** cooperate to send electrical stimulation signals to one or more of the stimulation electrodes provided on these instruments. Depending upon the location of the surgical access system **10** within a patient (and more particularly, to any neural structures), the stimulation signals may cause nerves adjacent to or in the general proximity of the surgical access system **10** to depolarize. This causes muscle groups to innervate and generate EMG responses, which can be sensed via the EMG harness **126**. The nerve direction feature of the system **120** is based on assessing the evoked response of the various muscle myotomes monitored by the system **120** via the EMG harness **126**.

By monitoring the myotomes associated with the nerves (via the EMG harness **126** and recording electrode **127**) and assessing the resulting EMG responses (via the control unit **122**), the surgical access system **10** is capable of detecting the presence of (and optionally the distant and/or direction to) such nerves. This provides the ability to actively negotiate around or past such nerves to safely and reproducibly form the operative corridor to a particular surgical target site, as well as monitor to ensure that no neural structures migrate into contact with the surgical access system **10** after the operative corridor has been established. In spinal surgery, for example, this is particularly advantageous in that the surgical access system **10** may be particularly suited for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column.

According to one embodiment, the surgical access system detects the presence of (and optionally, the distance and/or direction to) nerves by determining a stimulation current threshold level ("$I_{thresh}$") required to evoke a predetermined neuromuscular response (e.g. an EMG response of 100 uV). $I_{thresh}$ decreases as the degree of electrical communication between a stimulation impulse and a nerve increases. Thus, $I_{thresh}$ is indicative of the degree of communication between a stimulation source and a nerve and may therefore provide the user (by way of example only) with an indication of proximity to the nerve.

In order to quickly determine $I_{thresh}$, the system may employ a threshold-hunting algorithm. According to one embodiment, the threshold-hunting algorithm employs a series of monopolar stimulations to determine the stimulation current threshold for each EMG channel that is in scope. The nerve is stimulated using current pulses with amplitude of $I_{stim}$. The muscle groups respond with an evoked potential that has a peak to peak voltage of $V_{pp}$. $I_{thresh}$ is the minimum $I_{stim}$ that results in a $V_{pp}$ that is greater than a known threshold voltage $V_{thresh}$. The value of $I_{stim}$ is adjusted by a bracketing method as follows. The first bracket comprises two stimulation signals of different $I_{stim}$. By way of example the first bracket may comprise 0.2 mA and 0.3 mA. If the $V_{pp}$ corresponding to both of these stimulation currents is lower than $V_{thresh}$, then the bracket size is doubled to 0.2 mA and 0.4 mA. This exponential doubling of the bracket size continues until the upper end of the bracket results in a $V_{pp}$ that is above $V_{thresh}$. The size of the brackets is then reduced by a bisection method. A current stimulation value at the midpoint of the bracket is used and if this results in a $V_{pp}$ that is above $V_{thresh}$, then the lower half becomes the new bracket. Likewise, if the midpoint $V_{pp}$ is below $V_{thresh}$ then the upper half becomes the new bracket. This bisection method is used until the bracket size has been reduced to a predetermined accuracy. $I_{Thresh}$ may be selected from any value within the final bracket. By way of example, $I_{thresh}$ may be selected as the midpoint of the final bracket.

FIGS. **14-15** are exemplary screen displays (to be shown on the display **140**) illustrating one embodiment of the nerve direction feature of the monitoring system shown and described with reference to FIGS. **12-13**. These screen displays are intended to communicate a variety of information to the surgeon in an easy-to-interpret fashion. This information may include, but is not necessarily limited to, a display of the function **180** (in this case "DIRECTION"), a graphical representation of a patient **181**, the myotome levels being monitored **182**, the nerve or group associated with a displayed myotome **183**, the name of the instrument being used **184** (in this case, a dilator **46**, **48**), the size of the instrument being used **185**, the stimulation threshold current **186**, a graphical representation of the instrument being used **187** (in this case, a cross-sectional view of a dilator **46**, **48**) to provide a reference point from which to illustrate relative direction of the instrument to the nerve, the stimulation current being applied to the stimulation electrodes **188**, instructions for the user **189** (in this case, "ADVANCE" and/or "HOLD"), and (in FIG. **15**) an arrow **190** indicating the direction from the instrument to a nerve. This information may be communicated in any number of suitable fashions, including but not limited to the use of visual indicia (such as alpha-numeric characters, light-emitting elements, and/or graphics) and audio communications (such as a speaker element). Although shown with specific reference to a dilating cannula (such as at **184**), it is to be readily appreciated that the present invention is deemed to include providing similar information on the display **140** during the use of any or all of the various instruments forming the surgical access system **10** of the present invention, including the initial distraction assembly **12** (i.e. the K-wire **44** and dilators **46**, **48**), the speculum blades **20**, **22** and/or the retractor blades **90**, **92** and/or the guard members **114**.

The initial distraction assembly **12** (FIGS. **2-4**) may be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, the K-wire **44** may be equipped with a distal electrode **200**. This may be accomplished by constructing the K-wire **44** for a conductive material, providing outer layer of insulation **202** extending along the entire length with the exception of an exposure that defines the electrode **200**. As best shown in FIGS. **3-4**, the electrode **200** has an angled configuration relative to the rest of the K-wire **44** (such as, by way of example only, in the range of between 15 and 75 degrees from the longitudinal axis of the K-wire **44**). The

angled nature of the electrode **200** is advantageous in that it aids in piercing tissue as the K-wire **44** is advanced towards the surgical target site.

The angled nature of the distal electrode **200** is also important in that it provides the ability to determine the location of nerves or neural structures relative to the K-wire **44** as it is advanced towards or resting at or near the surgical target site. This "directional" capability is achieved by the fact that the angled nature of the electrode **200** causes the electrical stimulation to be projected away from the distal portion of the K-wire **44** in a focused, or directed fashion. The end result is that nerves or neural structures which are generally closer to the side of the K-wire **44** on which the electrode **200** is disposed will have a higher likelihood of firing or being innervated that nerves or neural structures on the opposite side as the electrode **200**.

The direction to such nerves or neural structures may thus be determined by physically rotating the K-wire **44** at a particular point within the patient's tissue and monitoring to see if any neural stimulation occurs at a given point within the rotation. Such monitoring can be performed via visual observation, a traditional EMG monitoring, as well as the nerve surveillance system disclosed in the above-referenced NeuroVision PCT Applications. If the signals appear more profound or significant at a given point within the rotation, the surgeon will be able tell where the corresponding nerves or neural structures are, by way of example only, by looking at reference information (such as the indicia) on the exposed part of the K-wire **44** (which reference point is preferably set forth in the exact same orientation as the electrode **200**).

Dilators **46**, **48** may also be provided with angled electrodes **204**, **206**, respectively, for the purpose of determining the location of nerves or neural structures relative to the dilators **46**, **48** as they are advanced over the K-wire **44** towards or positioned at or near the surgical target site. Due to this similarity in function with the electrode **200** of the K-wire **44**, a repeat explanation is not deemed necessary. The dilators **46**, **48** may be equipped with the electrodes **204**, **206** via any number of suitable methods, including but not limited to providing electrically conductive elements within the walls of the dilators **46**, **48**, such as by manufacturing the dilators **46**, **48** from plastic or similar material capable of injection molding or manufacturing the dilators **46**, **48** from aluminum (or similar metallic substance) and providing outer insulation layer with exposed regions (such as by anodizing the exterior of the aluminum dilator).

According to one aspect of the present invention, additional neural monitoring equipment may be employed so as to further prevent inadvertent contact with neural structures. For example, after the initial dilator **46** has been withdrawn in order to subsequently receive the mated speculum blades **20**, **22**, a confirmation probe (providing a stimulation signal) may be inserted through the outer dilator **48** and to a point at or near the surgical target site. The confirmation probe may thereafter be stimulated for the purpose of double-checking to ensure that no nerves or neural structures are disposed in the tissue near (or have migrated into the vicinity of) the distal end **54** of the outer dilator **48** before introducing the speculum blades **20**, **22**. By confirming in this fashion, the outer dilator **48** may be removed following the introduction of the speculum blades **20**, **22** and the secondary distraction performed (by coupling the handle assembly **24** to the blades **20**, **22** and expanding) without fear of inadvertently causing the speculum blades **20**, **22** to contact nerves or neural structures.

The secondary distraction of the present invention (FIGS. **5-6**) may be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, it may be advantageous to provide one or more electrodes along the speculum blades **20**, **22** and/or on the concave region **252** (such as stimulation electrode **208**) for the purpose of conducting neural monitoring before, during and/or after the secondary distraction.

The retractor blades **90**, **92** of the present invention (FIGS. **7-10**) may also be provided with one or more electrodes for use in providing the neural monitoring capabilities of the present invention. By way of example only, it may be advantageous to provide one or more electrodes **210** on the guard members **114** and/or the stimulation electrodes **212** on the locking members **36** (preferably on the side facing away from the surgical target site) for the purpose of conducting neural monitoring before, during and/or after the retractor blades **90**, **92** have been positioned at or near the surgical target site.

The surgical access system **10** of the present invention may be sold or distributed to end users in any number of suitable kits or packages (sterile and/or non-sterile) containing some or all of the various components described herein. For example, the pivot linkage assembly **14** may be provided such that the pivot amms **16**, **18** and speculum blades **20**, **22** are disposable and the retractor blades **90**, **92** are re-usable. In a further embodiment, an initial kit may include these materials, including a variety of sets of retractor blades **90**, **92** having varying (or "incremental") lengths to account for surgical target sites of varying locations within the patient.

## Spine Surgery Example

The surgical access system **10** of the present invention will now be described, by way of example, with reference to the spinal application shown in FIGS. **16-33**. It will, of course, be appreciated that the surgical access system and related methods of the present invention may find applicability in any of a variety of surgical and/or medical applications such that the following description relative to the spine is not to be limiting of the overall scope of the present invention. More specifically, while described below employing the nerve monitoring features described above (otherwise referred to as "nerve surveillance") during spinal surgery, it will be appreciated that such nerve surveillance will not be required in all situations, depending upon the particular surgical target site.

FIGS. **16-22** illustrate the method steps involved in using the initial tissue distraction assembly **12** of the present invention. The K-wire **44** is first introduced along a given pathway towards the surgical target site (which, in this case, is an intervertebral disc level of the lumbar spine). Determining the preferred angle of incidence into the surgical target site (as well as the advancement or positioning of any required surgical instruments (such as the surgical access system of the present invention), devices and/or implants) may be facilitated through the use of surgical imaging systems (such as fluoroscopy) as well any number of stereotactic guide systems, including but not limited to those shown and described in co-pending and commonly owned U.S. patent application Ser. No. 09/888,223, filed Jun. 22, 2001 and entitled "Polar Coordinate Surgical Guideframe," the entire contents of which is incorporated by reference as if set forth in its entirety herein.

Nerve surveillance is preferably conducted during this step (via electrode **200**) to monitor for the existence of (and optionally the distance and direction to) nerves or neural structures in the tissue through which the K-wire **44** must pass to reach the surgical target site. According to a preferred embodiment of the present invention, it is generally desired to advance the K-wire **44** such the distal electrode **200** is disposed a distance anterior to the exiting nerve root **300** (such

as, by way of example, 10 mm). As shown in FIGS. **16-17**, it is preferred to advance the K-wire **44** to the annulus **302** of the disc before advancing the inner dilator **46**. This is to prevent the unnecessary distraction of the psoas muscle **304** (which must be passed through in order to approach the surgical target site in the lateral or far-lateral approach shown) in the instance significant nerves or neural structures are encountered in the initial advancement of the K-wire **44**. If such nerves or neural structures are encountered, the K-wire **44** may simply be removed and re-advanced along a different approach path.

As shown in FIGS. **18-19**, once the K-wire **44** is safely introduced to the surgical target site, the inner dilator **46** may thereafter be advanced over the K-wire **44** until the distal end **52** abuts the annulus **302** of the disc. Nerve surveillance is also conducted during this step (via electrode **204** shown in FIGS. **3-4**) to monitor for the existence of (and optionally the distance and direction to) nerves or neural structures in the tissue through which the inner dilator **46** must pass to reach the surgical target site. Next, as shown in FIG. **22**, the K-wire **44** may be advanced through the annulus **302** such that the electrode **200** is disposed within the interior (nucleus pulposis region) of the disc (such as, by way of example, an internal distance of 15 to 20 mm).

With reference to FIGS. **21-22**, the outer dilator **48** is next advanced over the inner dilator **46** to further distract the tissue leading down to the surgical target site. As with the K-wire **44** and inner dilator **46**, nerve surveillance is conducted during this step (via electrode **206** shown in FIGS. **3-4**) to monitor for the existence of (and optionally the distance and direction to) nerves or neural structures in the tissue through which the outer dilator **48** must pass to reach the surgical target site.

With reference to FIG. **23**, the inner dilator **48** is next removed, leaving the K-wire **44** and outer dilator **48** in position. This creates a space therebetween which, in one embodiment of the present invention, is dimensioned to receive the speculum blades **20**, **22** as shown in FIGS. **24-25**. To accomplish this step, the speculum blades **20**, **22** must be disposed in an abutting relationship so as to form an inner lumen (via corresponding grooves **88** shown in FIG. **5**) dimensioned to be slideably advancing over the stationary K-wire **44**. Once again, as noted above, it may be desired at this step to advance a confirmation probe down the outer dilator **48** to interrogate the tissue surrounding the surgical target site to ensure that no nerves or neural structures are present in (or have migrated into) this vicinity before the speculum blades **20**, **22** are advanced into the outer dilator **48**.

Turning to FIGS. **26-27**, the outer dilator **48** may then be removed, leaving the speculum blades **20**, **22** in abutting relationship within the tissue previously distracted by the outer dilator **48**. As shown in FIGS. **28-29**, the pivot linkage assembly **14** may be advanced such that the pivot arms **16**, **18** slideably (or otherwise) pass over the speculum blades **20**, **22**. In one embodiment, the pivot arms **16**, **18** are dimensioned such that each distal end comes into general abutment with the exterior of the psoas muscle **304**. That said, it is within the scope of the invention to provide the pivot arms **16**, **18** such that each distal end extends downward into the psoas **304** towards the surgical target site (which may be advantageous from the standpoint of adding rigidity to the distal portions of the speculum blades **20**, **22** for the purpose of facilitating the process of secondary tissue distraction). Once positioned over the speculum blades **20**, **22**, the handle assembly **24** may be operate to distract tissue from the position shown in FIG. **28** to that shown in FIG. **29**.

As shown in FIG. **30**, the first retractor **90** is then introduced into the distracted region, positioned adjacent to the posterior region of the disc space, and locked to the pivot linkage **14** via the locking assembly **32**. At that point, the locking member **36** may be advanced via the tool **112** and engaged with the retractor blade **90** such that the middle region **108** resides at least partially within the passageway **102** and the distal region **110** extends into the disc space. Thereafter, as shown in FIG. **31**, the retractor blade **92** may be introduced into the distracted region, positioned adjacent to the anterior region of the disc space, and locked to the pivot linkage **14** via the locking assembly **34**. At that point, another locking member **36** may be engaged in the same fashion as with the retractor blade **90**, with the distal region **110** extending into the disc space. As shown in FIG. **32**, additional retractor blades **91**, **93** may be coupled to the pivot linkage **14** to provide retraction in the caudal and cephalad directions, respectively.

The end result is shown in FIG. **33**, wherein an operative corridor has been created to the spinal target site (in this case, the disc space) defined by the retractor blades **90**, **92** (and optionally **91**, **93**). The distal regions **110** of the locking each locking member **36** advantageously extends into the disc space to prevent the ingress of tissue (e.g., neural, vasculature, etc. . . . ) into the surgical target site and/or operative corridor and the egress of instruments or implants out of the surgical target site and/or operative corridor.

In a further protective measure, each retractor blade **90**, **92** is equipped with a guard member **114** to prevent similar ingress and egress. Both guard members **114** (as well as additional regions of the distal region **110** of the locking member **36**) may be provided with electrodes **210**, **212**, respectively, capable of performing nerve surveillance to monitor for the existence of (and optionally the distance and direction to) nerves or neural structures in the tissue or region surrounding or adjacent to these components while disposed in the general vicinity of the surgical target site. The electrode **210** on the guard member **114** of the posterior retractor blade **90**, in particular, may be used to assess the status or health of the nerve root **300**, especially if the nerve root **300** is in close proximity to that guard member **114**. This may be performed by using the nerve status determination systems or techniques disclosed in co-pending and commonly assigned U.S. Pat. No. 6,500,128, entitled "Nerve Proximity and Status Detection System and Method," the entire contents of which is hereby incorporated by reference as is set forth fully herein.

As evident from the above discussion and drawings, the present invention accomplishes the goal of providing a novel surgical access system and related methods which involve creating a distraction corridor to a surgical target site, thereafter retracting the distraction corridor to establish and maintain an operative corridor to the surgical target site, and optionally detecting the existence of (and optionally the distance and/or direction to) neural structures before, during and/or after the formation of the distraction and/or operative corridors.

The steps of distraction followed by retraction are advantageous because they provide the ability to more easily position an operative corridor-establishing device through tissue that is strong, thick or otherwise challenging to traverse in order to access a surgical target site. The various distraction systems of the present invention are advantageous in that they provide an improved manner of atraumatically establishing a distraction corridor prior to the use of the retraction systems of the present invention. The various retractor systems of the present invention are advantageous in that they provide an operative corridor having improved cross-sectional area and shape (including customization thereof) relative to the prior art surgical access systems. Moreover, by optionally equip-

ping the various distraction systems and/or retraction systems with one or more electrodes, an operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient.

The surgical access system of the present invention can be used in any of a wide variety of surgical or medical applications, above and beyond the spinal applications discussed herein. By way of example only, in spinal applications, any number of implants and/or instruments may be introduced through the working cannula **50**, including but not limited to spinal fusion constructs (such as allograft implants, ceramic implants, cages, mesh, etc.), fixation devices (such as pedicle and/or facet screws and related tension bands or rod systems), and any number of motion-preserving devices (including but not limited to nucleus replacement and/or total disc replacement systems).

While certain embodiments have been described, it will be appreciated by those skilled in the art that variations may be accomplished in view of these teachings without deviating from the spirit or scope of the present application. For example, with regard to the monitoring system **120**, it may be implemented using any combination of computer programming software, firmware or hardware. As a preparatory act to practicing the system **120** or constructing an apparatus according to the application, the computer programming code (whether software or firmware) according to the application will typically be stored in one or more machine readable storage mediums such as fixed (hard) drives, diskettes, optical disks, magnetic tape, semiconductor memories such as ROMs, PROMs, etc., thereby making an article of manufacture in accordance with the application. The article of manufacture containing the computer programming code may be used by either executing the code directly from the storage device, by copying the code from the storage device into another storage device such as a hard disk, RAM, etc. or by transmitting the code on a network for remote execution. As can be envisioned by one of skill in the art, many different combinations of the above may be used and accordingly the present application is not limited by the scope of the appended claims.

What is claimed is:

**1**. A method of accessing a surgical target site, comprising the steps of:

creating an initial distraction corridor through tissue extending between an incision point and a surgical target site via an initial distraction assembly including a K-wire and at least one dilator capable of being slideably passed over said K-wire;

distracting said tissue from said initial distraction corridor to a secondary distraction corridor with an instrument capable of being guided to said surgical target site along said at least one dilator of said initial distraction assembly;

introducing a plurality of retractor blades for retracting said tissue from said secondary distraction corridor to create an operative corridor to said surgical target site; and

providing a control unit capable of electrically stimulating at least one stimulation electrode provided on said initial distraction assembly, sensing a response of a nerve depolarized by said stimulation, determining at least one of nerve proximity and nerve direction from said initial distraction assembly to the nerve based upon the sensed response, and communicating to a user at least one of visual indicia and audio communications representing at least one of said determined nerve proximity and said determined nerve direction.

**2**. The method of claim **1**, wherein said instrument capable of being guided to said surgical target site along said at least one dilator of said initial distraction assembly comprises a secondary distraction system.

**3**. The method of claim **2**, wherein said secondary distraction system includes at least two speculum blades capable of being moved generally apart from one another.

**4**. A method of accessing a surgical target sites comprising the steps of:

creating an operative corridor through tissue extending between an incision point and a surgical target site via a distraction assembly and a retraction assembly, wherein said distraction assembly comprises an initial assembly including an elongate inner element and at least one dilator, said distraction assembly further comprises a secondary instrument advanceable to said surgical target site along said at least one dilator of said initial assembly, and wherein at least one of said distraction assembly and retraction assembly includes at least one stimulation electrode;

electrically stimulating said at least one stimulation electrode;

sensing a response of a nerve depolarized by said stimulation;

determining at least one of nerve proximity and nerve direction of said nerve relative to at least one of said distraction assembly and said retraction assembly based upon the sensed response; and

communicating indicia to a user representing at least one of said determined nerve proximity and said determined nerve direction.

**5**. The method of claim **4**, wherein said operative corridor is established to a spinal target site.

**6**. The method of claim **4**, wherein said operative corridor is established to a spinal target site via a lateral, trans-psoas approach.

**7**. The method of claim **4**, wherein communicating to a user includes displaying at least one of alpha-numeric characters, light-emitting elements and graphics representing an electromyographic (EMG) response of the muscle.

**8**. The method of claim **4**, wherein communicating to a user includes audibly communicating sounds representing an electromyographic (EMG) response of the muscle.

**9**. The method of claim **4**, wherein said step of determining at least one of nerve proximity and nerve direction includes determining a threshold stimulation level required to evoke said neuromuscular response and wherein said step of determining a threshold stimulation level includes establishing first a bracket containing said threshold stimulation level and bisecting said bracket to form a smaller second bracket containing said threshold stimulation level.

* * * * *

## Certificate of Service

I hereby certify that I electronically filed the foregoing with the Clerk of the Court of the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on October 20, 2014.

October 20, 2014

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## Certificate of Compliance with Rule 32(a)

This brief complies with the type-volume limitation of Rule 32(a) of the Federal Rules of Appellate Procedure because it contains 10,897 words.

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